MEDICAL COMMISSION EDUCATIONAL WORKSHOP

The Evolution of Medicine:
Improving Patient Safety

October 2-3, 2013
Capital Event Center Tumwater, WA

A public service of the Washington State Medical Commission

Washington State Department of Health

Washington State Medical Commission
2013 Educational Conference

The Evolution of Medicine-Improving Patient Safety

WEDNESDAY – October 2, 2013 – Capital Event Center	
8:15 a.m.	**Welcome: Richard D. Brantner, MD FAAEM** Chair, Washington State Medical Commission
8:30 a.m.	**Michael Tronolone, MD, MMM** Chief Medical Officer, The Polyclinic *Journey to becoming the first Accountable Care Organization in Washington*
9:30 a.m.	**Break**
9:45 a.m.	**Ann C. Greiner** Vice President External Affairs, National Quality Forum *Patient Safety: How can the Commission move from policy to results*
10:45 a.m.	**Thomas H. Gallagher, MD** Professor, UW School of Medicine *Disclosure and Resolution Program and its application to the Commission*
12:30 p.m.	**Presentation: Robert Crittenden, MD** Executive Policy Advisor to the Governor Washington State Health Strategy and the Role of Patient Safety **Introduction: Jason McGill, JD** Policy Advisor to the Governor
1:30 p.m.	**Networking break**
2:00 p.m.	**Commission Senior Management** *Medical Commission performance and efforts update*
3:00 p.m.	**Thomas McPhee, JD** Thurston County Superior Court (ret.) **Jeffrey Jahns, JD** Kitsap County District Court *Resolving conflicting testimony: A judicial perspective* **Moderator: Tracy L. Bahm, AAG** Chief Prosecutor, Washington State Attorney General
4:15 p.m.	**Wrap up and discussion**

Washington State Medical Commission
2013 Educational Conference

THURSDAY – October 3, 2013 – Capital Event Center	
8:15 a.m.	**Welcome: Richard D. Brantner, MD FAAEM** Chair, Washington State Medical Commission
8:30 a.m.	**Charles Meredith, MD** Medical Director, Washington Physicians Health Program *Dealing with the disruptive physician*
9:30 a.m.	**Break**
9:45 a.m.	**Heather Tick, MD** Clinical Associate Professor, UW School of Medicine *Integrative Medicine and Mitigation of Risk*
10:30 a.m.	**Glen O. Gabbard, MD** Clinical Professor of Psychiatry, The Gabbard Center **Gabrielle S. Hobday, MD** Forensic Psychiatrist, The Gabbard Center *An overview of sexual misconduct*
12:30 p.m.	**Presentation: Scott M. Fishman, MD** Chair: Pain Medicine, Vice Chair: Anesthesiology U.C. Davis School of Medicine *Opioid and Prescription Drug Abuse* **Introduction: Jon V. Thomas, MD, MBA** Chair, Federation of State Medical Boards
1:30 p.m.	**Networking Break**
2:00 p.m.	**Glenn O. Gabbard, MD and Gabrielle S. Hobday, MD** *The continuum of professional boundary violations*
3:00 p.m.	**Jon Thomas, MD, MBA** Federation of State Medical Boards, Chair *FSMB policy presentation: Maintenance of licensure and telehealth*
3:45 p.m.	**Closing:** *Conference debriefing and wrap-up*
FRIDAY – October 4, 2013- PPE, Rooms 152 and 153	
8:00 a.m.-8:30 a.m.	Commission Business Meeting
8:30 a.m.-12:00 p.m.	Case Reviews (closed session)

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Washington State Medical Commission 2013 Educational Conference Evaluation

Please select or highlight the choice that best fits your answer.

1. How satisfied were you with the conference materials provided?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
2. Overall, how satisfied were you with the speakers/presenters?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
3. Overall, how satisfied were you with the conference facilities?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
    f. Other comment:
4. Overall, how satisfied were you with the conference refreshments offered?
    a. Very Satisfied
    b. Satisfied
    c. Neutral
    d. Dissatisfied
    e. Very Dissatisfied
    f. Other comment:
5. How many sessions did you attend?
    a. 1-3
    b. 3-5
    c. 5-7
    d. All day, October 2
    e. All day, October 3
6. How did you feel about the length of the conference sessions?
    a. Too short
    b. Just about right
    c. Too long
    d. Other comment:

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Please tell us how much you agree or disagree with the following statements:

7. The content of the conference sessions is appropriate and informative.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

8. The conference is well organized.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

9. Conference and Commission staffs are helpful and courteous.
    a. Strongly agree
    b. Agree
    c. Neutral
    d. Disagree
    e. Strongly Disagree
    f. Other Comment:

10. What kinds of sessions would you like to see included at future conferences?

11. What did you like most about the conference?

12. What did you like least about the conference?

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13. Approximately how many conferences of this type do you attend annually?
    a. 1-2
    b. 3-4
    c. 5-6
    d. More than 6
    e. Don't usually attend these types of conferences

14. Do you plan to attend the conference again?
    a. Yes
    b. No
    c. Don't know

15. If the conference required registration would you attend?
    a. Yes
    b. No
    c. Don't know

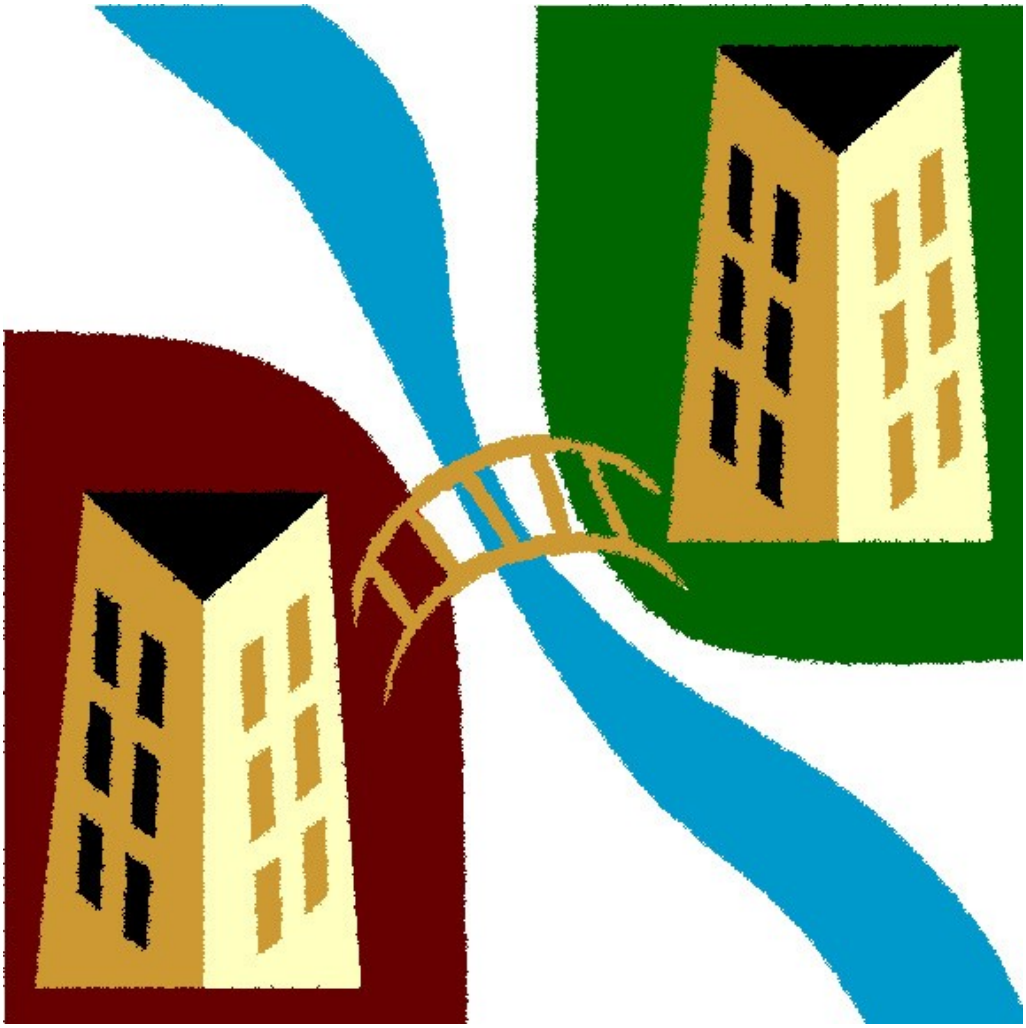
16. If the conference required a fee but granted CME, would you attend?
    a. Yes
    b. No
    c. Don't Know
    d. Other Comment:

17. How would you rate this conference compared to other conferences that you have attended?
    a. Excellent
    b. Very good
    c. Average
    d. Poor
    e. Very poor

18. In what ways could we improve this conference?

Thank you for completing this survey of the 2013 educational conference. Please place the completed survey in the basket on the registration table or send the completed electronic version to Micah.Matthews@doh.wa.gov.

Transitioning to Accountable Care



Incremental Payment Reforms to Support Higher Quality, More Affordable Health Care

Harold D. Miller

Center for Healthcare Quality & Payment Reform

The Commonwealth Fund

ABOUT THE AUTHOR

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TRANSITIONING TO ACCOUNTABLE CARE:
Incremental Payment Reforms to Support Higher Quality, More Affordable Health Care

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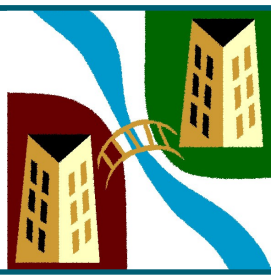
EXECUTIVE SUMMARY

TRANSITIONING TO ACCOUNTABLE CARE:

INCREMENTAL PAYMENT REFORMS TO SUPPORT HIGHER QUALITY, MORE AFFORDABLE HEALTH CARE



There is growing agreement that many of the cost and quality problems in health care today are either caused or exacerbated by the way we pay for health care services. Although a variety of payment reforms have been proposed to address these gaps, many of them are seen either as doing too little to address the problems caused by current payment systems or as changing payment too radically for providers to easily implement.

There is a need for "middle-ground" options – payment reforms that provide greater flexibility and accountability for care than typical pay-for-performance, shared savings, and medical home programs, but which avoid forcing providers to take on more financial risk than they can manage or to take accountability for services they cannot effectively control (as traditional capitation systems or full episode-of-care payment systems can require). These middle-ground changes can be viewed as *transitional payment reforms*, i.e., they enable healthcare providers to deliver some improvements in cost and quality for payers and patients as the providers build the capacity to transition to more comprehensive payment reforms in a way that is feasible for them.

PAYMENT REFORMS TO SUPPORT ACCOUNTABLE ACUTE CARE

There are at least seven different types of payment reforms that could be used by providers and payers to transition toward more episode-oriented payment structures for major acute care:

- **Paying hospitals on a case rate basis for all patients**, i.e., using DRG-type payments in place of per diem and charge-based payments for all patients;
- **Paying all physicians on a case rate basis for acute care episodes**, i.e., making a single payment to a physician for all services during an entire patient stay, similar to the way surgeons and obstetricians are currently paid;
- **Bundling payments to hospitals and physicians**, i.e., making a single payment for both hospital and physician services instead of separate payments;
- **Providing an inpatient warranty**, i.e., having hospitals and/or physicians agree not to charge more for services to correct errors, infections, and other hospital-acquired complications;
- **Bundling payments for inpatient and post-acute care**, i.e., paying a single amount to cover both inpatient care and services after discharge such as inpatient rehabilitation and home health care;
- **Providing a warranty for post-discharge complications and readmissions**, i.e., having hospitals and/or physicians agree not to charge more for preventable readmissions to the hospital; and
- **Paying based on diagnosis instead of treatment**, i.e., defining DRGs and physician case rates based on patient diagnoses, rather than on the specific procedures or treatments performed.

These transitional payment reforms need not be pursued in any particular sequence, and different approaches can be used with different types of patients and conditions. The goal should be to change the payment structure in the most targeted way possible to enable specific problems with care to be solved or specific goals to be achieved. For example, if there are inefficiencies in the way care is delivered, bundling payments could be the best approach for solving that, whereas if infection rates are high, a warranty would be a more appropriate approach.

PAYMENT REFORMS TO SUPPORT ACCOUNTABLE MEDICAL HOMES AND SPECIALTY CARE

Three payment changes that could help primary care and specialty physician practices transition toward more global payment structures are:

- **Paying Primary Care Practices with Care Management Payments and Utilization-Based Performance Incentives.** This would involve adding three new components to fee-for-service payments for primary care:
  - A Care Management Payment would be paid to the primary care practice for each patient (in addition to current fees for individual services) to support better patient education and self-management support, access to physicians by telephone, etc.;

- Specific targets for reducing utilization of healthcare services outside of the practice (e.g., non-urgent emergency room visits, ambulatory care sensitive hospitalizations, and/or high-tech diagnostic imaging) would be established that would result in savings greater than the cost of the Care Management Payment; and
- Bonuses/penalties would be paid to the practice based on its performance against the targets.

- **Paying Specialists with Care Management Payments and Utilization-Based Performance Incentives.** Similar to the payment model above for primary care practices, specialists would be paid more to better manage and coordinate patient care, but with specific targets for reducing utilization of expensive services such as hospital care.
- **Paying Physician Practices with Condition-Specific Partial Comprehensive Care Payments.** A physician practice or group of providers would be paid a single amount for most or all of the services that a patient will need from more or all providers for one or more of the patient's health conditions over a fixed period of time (e.g., a year). This would replace separate fees currently paid for the individual services that are covered by the payment.

Setting Prices, Managing Risk, and Ensuring Quality

For any of the transitional payment reform steps, as well as for full episode or global payment, three additional issues must be addressed:

- **Establishing an appropriate payment amount (i.e., a price) for each patient or group of patients.** Even if the payment method provides the right incentives for better care, if the payment level is too low (i.e., below the minimum feasible cost of providing care), providers will be unable to provide quality care, and if the payment level is too high, there will be no real incentive for efficiency. A major challenge here is getting adequate data to enable both providers and payers to determine what appropriate prices are for new payment systems.
- **Limiting the financial risk associated with unusually expensive patients or with costs that the provider cannot control.** Four methods could be used to do this:
  - **Condition/Severity Adjustment**, i.e., paying a provider different amounts depending on the type and severity of the patient's health conditions;
  - **Outlier Payments/Adjustments**, i.e., paying a provider more when the cost of caring for a patient exceeds a certain threshold, or not holding the provider accountable for the total cost or quality of care for patients with unusual conditions;
  - **Risk Corridors**, i.e., limiting the extent to which the cost of actual service delivery for a group of patients can differ from the payment amount; and
  - **Exclusions and Risk-Sharing With Other Providers**, i.e., excluding the costs of services delivered by some outside providers from the payment, or having two providers each accepting accountability for different portions of the total costs of caring for a group of patients.
- **Ensuring that the quality of care to patients is maintained or improved as incentives to control costs are introduced.** The types of explicit quality incentives needed will depend on the specific payment model used, but it is likely that current efforts to measure the quality of preventive care will be a critical complement to all new payment models.

Developing a Transition Strategy

Ideally, a community should start by focusing transitional payment reforms on areas where significant cost savings can be achieved quickly. The following four criteria can help identify where the likelihood of significant, short-term success is highest:

- Conditions which affect a large number of patients;
- Services where there is evidence of overutilization or inefficiency involving relatively large amounts of spending;
- Changes in care that have been proven to reduce overutilization or inefficiency, that are relatively simple or low-cost to implement, that can achieve significant results within a relatively short time period, ideally a year, and that are viewed favorably by patients; and
- Services, conditions, and care changes where there is strong clinical leadership in the community.

When developing a transitional payment strategy, it is important to try and define not only the *initial* incremental steps, but also the desired *end point* (i.e., the payment system that is ultimately to be used) and as many of the intermediate steps as possible, so that both providers and payers understand how investments made today will pay returns in the future.

The transitional payment models can also serve as important building blocks for Accountable Care Organizations (ACOs). The most important factors in the success of ACOs will be (1) their ability to identify specific opportunities for improving the way care is delivered to patients that can reduce costs and improve quality, and (2) their ability to provide

the resources and supports that individual healthcare practitioners need to enable and encourage them to make those improvements. An ACO cannot control *total* costs and quality if it cannot control the costs and quality of individual episodes of care and the number of episodes for groups of patients, and it cannot control those things if the individual practitioners who deliver the care are still being paid based on volume rather than value. Even if the ACO is accepting a global payment for the total costs of care for a patient population, it will need to break that payment down and use it to make the equivalent of episode payments and comprehensive care payments to the individual physician groups and other providers involved in delivering the care.

Obtaining Support From Payers

Since providers need better payment systems in order to deliver higher-value care, it will be essential to have payers offer a range of transitional payment options in order to allow all of the providers in a community to transform their care. Although it might seem much easier and cheaper to try and choose one "best" payment system and stick to it over a long period of time, any one-size-fits-all payment change would mean that (1) those providers who could accept greater accountability than permitted by the payment change would be unable to deliver all of the improvements in value they could offer, and (2) those providers without sufficient skills to participate in the payment model that is chosen would be unable to make even the small improvements in value they could offer if given the opportunity to participate in a more incremental payment reform. Consequently, multiple payment models will likely need to be available in many communities to support providers with different capabilities.

In addition, as many payers in a community as possible need to implement the *same* payment reforms. It is in both payers' and providers' interests for all payers to adopt a new payment arrangement, since this would enable a healthcare provider to change its care processes for all of its patients without being financially penalized for any of them, while also avoiding creating a competitive disadvantage for an individual payer which makes payment changes if the other payers do not. However, achieving alignment of all payers in a market is very challenging because of antitrust concerns and the fact that it is costly for national payers to implement different payment systems in different communities. Some approaches that could be used to achieve a critical mass of multi-payer alignment for providers include:

- Use state government or a non-profit Regional Health Improvement Collaborative to facilitate agreement on a common payment methodology.
- Reach agreement on a common approach to payment reforms first among payers who exclusively or primarily pay for patients living in the local market.
- Restructure payment for types of patients and conditions for which there are fewer payers or payers who are more willing to change their payment systems.
- Implement payment reforms with providers who accept payment from a more narrow range of payers.
- Implement payment reforms initially with providers which have their own health plan.
- Define the most critical aspects of payment systems that need to be aligned, rather than trying to get all payers to implement identical payment systems.

Because of its size, participation by the Medicare program is extremely important. Fortunately, the federal Patient Protection and Affordable Care Act (PPACA) has given the Centers for Medicare and Medicaid Services the power to offer the full range of transitional payment reforms described above if it wishes to do so. The two principal sections of the law that provide this capability are:

- **Shared Savings Program/Accountable Care Organizations (ACOs).** Although titled the "Shared Savings Program," Section 3022 of PPACA (Section 1899 of the Social Security Act) provides the Secretary of Health and Human Services with the power to establish "other payment models" for Accountable Care Organizations that the Secretary determines "will improve the quality and efficiency" of healthcare, as long as payments do not result in spending more "than would otherwise be expended … if the model were not implemented, as estimated by the Secretary." Each of the transitional payment reform models described above can be structured in a way that maintains or reduces spending for the services encompassed by the payment. Moreover, the law does not require that ACOs provide or control provision of all services, merely that an ACO must "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it;" this could easily include organizations that are willing to transition over time to broad accountability but need more narrowly defined initial payment reforms to enable them to get started.
- **Center for Medicare and Medicaid Innovation.** Section 3021 of the law creates this new entity and gives it the power and duty "to test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care…" This will also allow Medicare to participate in unique payment models developed in individual communities to help their providers transition to more accountable care.

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I. The Need for Transitional Payment Reforms

A. The Barriers to High Quality, Affordable Care Posed By Current Payment Systems

There is growing agreement that many of the cost and quality problems in health care today are either caused or exacerbated by the way health care services are paid for. Under most current healthcare payment systems:

- Physicians, hospitals, and other healthcare providers receive more revenue for delivering more services, not for delivering higher quality services or services which are more effective in improving a patient's health, i.e., providers are paid for doing *more,* not *better*.
- Healthcare providers may actually be financially penalized for improving the quality of their services. For example, reducing errors and complications can not only reduce providers' revenues, but also reduce their profits and ability to remain financially viable.[1] Moreover, under most payment systems, health care providers make less money if a patient stays healthy.
- Separate payments are made to each physician, hospital, and other healthcare provider involved in a patient's care, which can result in duplication of tests and services for the same patient[2], with no incentive for separate providers to coordinate their services.
- Many valuable preventive care and care coordination services are not paid for adequately (or at all)[3], which can result in unnecessary illnesses and treatments. In addition, low payment levels are believed to be discouraging physicians from entering primary care, contributing to shortages of primary care physicians in many areas.

B. The Problems With Many Payment Reform Proposals

Although a variety of payment reforms have been proposed to address these gaps, the major proposals either do too little to address the problems caused by current payment systems or change payment systems too radically for many providers to easily implement. For example:

- **Pay-for-Performance Programs.** Many health plans are using pay-for-performance (P4P) programs to reward physicians and hospitals for achieving better performance, and the federal Patient Protection and Affordable Care Act has authorized Medicare to implement such programs. However, these programs typically do nothing to change the problems and undesirable incentives in the underlying payment system, and if they provide bonuses on top of existing payments, they require payers to spend more than they are spending today. As a result, the amount of funding involved is relatively small relative to the overall revenues that a provider will receive, creating relatively little incentive for improvement, particularly since the underlying fee-for-service incentives remain in place.[4]
- **Shared Savings Programs.** "Shared savings" programs are intended to address some of the weaknesses with traditional P4P systems by paying a bonus to providers that is explicitly connected to the amount by which they reduce the total cost of care for their patients compared to expected levels. Because the provider's bonus payment is directly related to the payer's savings, a shared savings program avoids directly increasing costs, and gives a provider the potential for receiving significant bonuses. However, like other P4P programs, a shared savings program does not provide any higher payment up front or any greater flexibility in the basic payment system to enable providers to change the way they deliver services. Most physician practices do not have sufficient financial reserves or access to working capital to enable them to afford to hire the staff, install the information technology, etc. needed to significantly reduce costs elsewhere in the healthcare system, particularly based on the uncertain prospect of a shared savings payment that will only arrive a year or more after the expenses are incurred. In addition, because total costs must decrease (or increase more slowly than projected) in order for bonuses to be paid, it may be impossible for an individ-

ual provider to receive a shared savings bonus, even if it is controlling or reducing the portions of costs it can control, if other providers in the system are not behaving similarly (e.g., a primary care practice might receive no reward for a successful program to reduce hospitalizations of chronic disease patients if the local hospital is simultaneously working to encourage specialists to increase admissions for elective procedures). Because there is no change in the underlying payment system, all of the existing weaknesses of the current payment system remain, and even though shared savings payments could be higher than the bonuses under many P4P programs, it is still unlikely that they can overcome the problematic incentives built into the current system.[5]

"Shared Savings" is merely a new form of Pay-for-Performance that leaves all of the Weaknesses of the fee-for-service system in Place

- **Medical Home Payment Programs.** A number of programs have been created to provide additional payments to primary care practices so they can restructure their services to be consistent with the principles of the Patient-Centered Medical Home (PCMH).[6] However, many payers have been reluctant to make payments of any significant size to medical homes merely for meeting accreditation standards as a PCMH without evidence that the practice will actually reduce the costs of other services not delivered by the physician practice, such as preventable hospitalizations and emergency room visits.[7] Consequently, the payment levels for medical home services may be lower than needed to significantly change the way care is delivered.

At the other extreme, some payment systems are viewed as being too radically different from fee-for-service for many providers to participate in, at least in the near term. For example:

- **Capitation/Global Payment.** Traditional "full risk" capitation and global payment systems provide considerable flexibility for providers to change the way services are delivered, but they also require the provider to be able to control or manage the costs of all aspects of a patient's care, and they put the provider at financial risk for having patients who are sicker than average or have rare or unusually complex conditions. Most small providers do not have the size, scope, or financial capacity to manage such payment systems without outside assistance.
- **Episode-of-Care Payment.** "Episode-of-Care Payments" have been proposed that would define a single payment for all of the services associated with a hospitalization or other episode of acute care, including both inpatient and post-acute care and any services needed to treat errors or adverse events during the patient's care. However, successfully managing these payments requires controlling the actions of a number of independent healthcare providers (hospitals, physicians, post-acute care providers, etc.), and because of the variability in the number and types of services from episode to episode, determining a fair price for such episodes is very challenging.

C. The Need for Transitional Payment Reforms

Clearly, there is a need for "middle-ground" options – payment reforms that provide greater flexibility and accountability for care than typical pay-for-performance, shared savings, and medical home programs, but which avoid forcing providers to take on more financial risk than they can manage or to take accountability for services they do not have effective mechanisms for controlling (the way traditional capitation systems or full episode-of-care payment systems would require). These middle-ground changes can be viewed as *transitional payment reforms*, i.e., they enable healthcare providers to deliver some improvements in cost and quality for payers and patients as the providers build the capacity to transition to more comprehensive payment reforms, such as capitation or episode-of-care payment, in a way that is feasible for them.

In most communities in the nation, the majority of primary care physicians, specialists, and hospitals are relatively small, independent entities, not large integrated systems. Consequently, transitional payment reforms are particularly important so that these providers can immediately begin to take accountability for the subset of costs they can realistically expect to control today, while building the capacity to control a greater share of costs in the future.

Section II will examine transitional payment reforms which enable and encourage hospitals and specialists to reduce the costs and improve the quality of major acute care episodes, e.g., treating a serious injury, replacing an arthritic hip or knee, facilitating childbirth, responding to a heart attack, or treating a curable cancer. There is considerable evidence that the costs of many acute care episodes can be reduced while maintaining or improving quality, e.g., by increasing co-

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operation among hospitals, physicians, and other providers, by using lower cost treatment options, by reducing adverse events (such as complications and infections), and by reducing preventable readmissions, if payment systems can be structured in a way to support the necessary changes in care delivery.

Section III will examine transitional payment reforms which enable and encourage primary care practitioners and specialists to reduce the costs and improve the quality of care for a wide range of patients. There is evidence that both short-run and long-run healthcare costs can be reduced for many types of patients, e.g., by improving prevention and early diagnosis, by reducing unnecessary testing, referrals and medications, and by reducing preventable emergency room visits and ambulatory care-sensitive hospitalizations, if primary care practitioners, specialty physicians, and other providers can be paid in ways that support the necessary changes in care delivery.

Appropriately Structured Transitional payment reforms can enable small providers to immediately take accountability for the subset of costs they can realistically expect to control today, while building the capacity to control a greater share of costs in the future

Some important aspects of transitional payment reforms, such as pricing, risk limits, and quality assurance are common to both payments for major acute care, primary care, and specialty care, and these will be addressed in Section IV. Section V will discuss how multi-step transition processes could be developed that match the specific opportunities and capabilities of different providers and communities, and how these transitional payment reforms can serve as the building blocks for "Accountable Care Organizations." Finally, Section VI will examine the importance of having a range of payment changes made in a consistent fashion by all payers in a community.

II. Payment Reforms to Support Accountable Acute Care

There has been considerable interest in payment reforms for major acute care (e.g., treating a serious injury, replacing an arthritic hip or knee, facilitating childbirth, responding to a heart attack, or treating a curable cancer), partly because so much of healthcare spending is devoted to hospital and post-acute care, and partly because so many opportunities have been identified for both improving the quality and reducing the costs of such care, such as reducing infections, complications, and readmissions and improving the efficiency and coordination of care. Episode-of-Care Payment is designed to help address these opportunities by defining a single payment for all of the services from all providers associated with a hospitalization or other episode of acute care, including any services needed to treat errors or adverse events during the patient's care.[8]

A full episode-of-care payment makes three key types of changes from current payment systems:

- It combines payments for two or more services delivered during the episode which are currently paid for separately (e.g., multiple visits by a single physician) into a single payment;
- It combines payments for two or more providers involved in the episode who are currently paid separately (e.g., hospitals, doctors, and post-acute care providers) into a single payment;
- It may combine payments for treatment of two or more related patient conditions or diagnoses which are currently paid for separately (e.g., the condition that led to the hospitalization and complications which arise during the hospitalization) into a single payment.

A major reason why such a payment is viewed as challenging for both payers and providers is it makes these three significant types of changes at once, affecting many providers and many services in complex ways.

However, although all of these types of changes may be desirable, it is not essential that they all be made at the same time; indeed, one approach to transitioning to a full episode-of-care payment system would be to make one or more of these changes without the others. Moreover, a single change may enable significant improvements in cost and quality, and it may be possible to achieve savings more quickly by taking incremental steps than by trying to implement a complete episode-of-care payment system all at once.

There are at least seven different types of steps that could be taken by providers and payers to transition towards more episode-oriented payment structures for major acute care:

- Paying hospitals on a case rate basis for all patients;
- Paying all physicians on a case rate basis for acute care episodes;
- Bundling payments to hospitals and physicians;
- Providing an inpatient warranty;
- Bundling payments for inpatient and post-acute care;
- Providing a warranty for post-discharge complications and readmissions; and
- Paying based on diagnosis instead of treatment.

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A. Paying Hospitals on a Case Rate Basis for All Patients

In 1983, Medicare took a major step toward episode payment for major acute care by creating the Inpatient Prospective Payment System, commonly known as DRG (Diagnosis Related Group) payment. Previously, all hospitals were paid based on their incurred costs, which provided little incentive to control costs. Under the DRG system, hospitals receive a single "case rate" payment for a patient stay, which gives the hospital a strong economic incentive to control its costs so that they are less than the payment amount.[9]

Although Medicare instituted the DRG payment system nearly 30 years ago, and although many private health plans and Medicaid programs followed in Medicare's footsteps, a number of private health plans and Medicaid programs across the country still pay large hospitals on a per diem basis (i.e., the hospital is paid an additional amount for each day the patient is in the hospital) or on a percent-of-charges basis (i.e., the hospital is paid more for each individual service delivered to the patient). These systems create far less incentive for hospitals to control their costs than the DRG system, and for many hospitals, it appears that rather than reducing costs to stay within Medicare payment levels, they merely shift costs to other payers who use non case-rate payment systems.

Consequently, one obvious transitional step is for hospitals to be paid on a case rate basis, such as the DRG system, for *all* of their patients, including self-pay patients. This could not only generate savings for the payers who make the switch, but could create more consistent incentives across the hospital's entire patient population and reduce the hospital's administrative costs needed to manage multiple payment systems. For example, the State of Maryland requires that hospitals be paid on a DRG-type basis for all of their patients, regardless of payer.[10] Recent refinements to the DRG system (e.g., the MS-DRG system used by Medicare, and the APR-DRG system used by many commercial payers) have improved the ability of this payment system to match differences in patient needs.

B. Paying All Physicians on a Case Rate Basis for Acute Care Episodes

Even when hospitals are paid a single amount for all of the hospital services associated with a patient's hospital stay, Medicare and other payers typically pay most physicians on a fee-for-service basis for the care they deliver during that same hospital stay, i.e., the physician gets an additional payment for each additional service that he or she provides to the patient in the hospital. The more services provided, the more payment the physician receives, and the longer the patient stays in the hospital, the more opportunity there is for physicians to provide additional services, even if it is merely a daily visit to see how the patient is doing.

Some physicians, however, are paid in a fashion similar to the way hospitals are paid under DRGs. Surgeons typically receive a "case rate" or "global fee," i.e., they receive a single payment to cover all of their services to a particular patient for a specific episode of care. Similarly, obstetricians are typically paid this way for maternity care – they receive a single payment that covers prenatal care, labor and delivery, and post-partum care for a mother's pregnancy.

The case rate approach could be expanded to other physicians. For example, when a patient is admitted to the hospital for treatment of pneumonia, the physician managing the patient's care (either a primary care physician or a hospitalist or another specialist) could be paid a single amount for the patient's treatment, similar to the single DRG payment the hospital will receive for the patient's treatment from Medicare and many other payers.

This can have advantages for both payers and physicians:

- From a payer's perspective, it creates an incentive for the individual physician to eliminate unnecessary services, since the payment remains the same regardless of how many individual services are delivered during the episode of care or period of time for which the combined payment is being made.
- From the physician's perspective, a case rate payment provides more flexibility to customize services to what a patient needs without regard to the impact of delivering more or fewer services on the physician's revenue and the patient's cost-sharing. In addition, it may reduce or eliminate the need to bill for each individual service provided, and

it can provide greater predictability of revenues for the physician (since payment will not vary based on the exact number of services a patient happens to need).

C. Bundling Payments to Hospitals and Physicians

Today, when a patient is hospitalized, at least two separate payments are made for the costs of their hospitalization – one to the hospital, and one to the physician who treated them in the hospital. (See Figure 1.) In many cases, more than one physician will be involved in the patient's care, which means that more than two separate payments will be made.

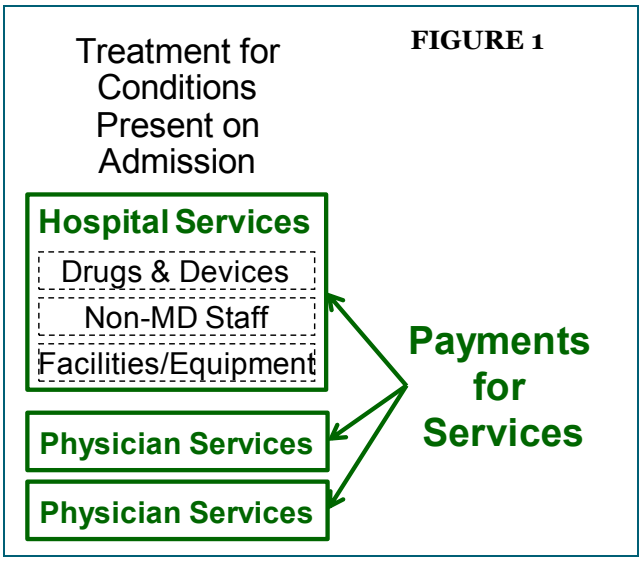

FIGURE 1

This structure creates three major types of problems:

- Even though the hospital and the physician(s) are each clearly dependent on each other for the patient's care, there is no financial incentive for the physicians to help find ways to lower the hospital's costs, because the physicians are not responsible for paying for those costs. Lowering the hospital's costs (e.g., by reducing the number or costs of drugs or devices used for patient treatment) improves the hospital's profit margin, but it does nothing to improve the physician's own profit margin, since the physician's costs and fees remain the same. In some cases, reducing the hospital's costs could reduce the physician's revenues, e.g., if the patient is discharged from the hospital earlier and thereby receives fewer visits from the physician. (The current payment system also gives the hospital no financial incentive to help the physicians lower *their* costs; however, because hospital costs and payments for treating a patient are generally so much larger than the payments and costs for a physician, the biggest lost opportunities are likely on the hospital side.)
- There is no financial incentive for multiple physicians to better coordinate their activities; indeed, finding a way to reduce the number of physicians involved in a patient's care, or reducing the frequency with which they see the patient, would merely reduce revenues for one or more of them with no increase in payment to the remaining physicians, and could potentially cause more work for one or more of them with no increase in compensation.
- It is impossible for consumers and payers to determine the total cost of care in any hospital or to compare costs across hospitals. Even if the consumer or payer knows in advance what fees the hospital and physicians charge for their individual services, they will not know the total cost of the hospitalization in advance, since that will depend on how long the patient was in the hospital and how many physicians were involved during their stay.

These problems can be solved or mitigated by "bundling" the payments to the hospital and physicians into a single payment covering all services provided in the hospital, whether those services are delivered by hospital staff or by the physicians. (See Figure 2.) For example, if a patient has hip replacement surgery, rather than having one payment to the hospital, a second payment to the surgeon, a third payment to the anesthesiologist, and potentially additional payments to other consulting physicians, Medicare, Medicaid, or a health insurance plan would make a single "bundled" payment for all of these services, and it would be up to the hospital, surgeon, anesthesiologist, etc. to determine how to

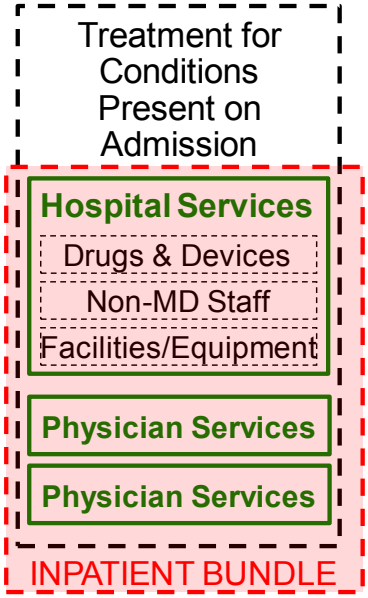

FIGURE 2

"Bundled Payment" = Making a single payment for both hospital and physician services instead of separate DRG or per diem payments to hospitals and case rates or fees to individual physicians

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divide that payment among themselves. Under bundled payment, the surgeon and the anesthesiologist both have an incentive to help the hospital lower its costs, because they would have the ability to share in the hospital's savings, which they do not today.[11]

It is easier to bundle a hospital's and physician's payments if the hospital and physician are already each being paid a single case rate for the patient's stay (e.g., for surgery where the hospital is paid on a DRG basis and the surgeon is paid a global fee) than if the hospital is being paid on a per diem basis and/or the physician is being paid fees for individual services. (This is why most payment bundling projects to date have been focused on surgery.) Consequently, bundling would be facilitated if the transitional steps in Sections II-A and II-B had already been taken.

A challenge in implementing bundled payments is reaching agreement on which entity will receive the combined payment. Physicians who are not employed by hospitals will likely resist having hospitals accept bundled payments and then pay the physicians their share; hospitals will likely be equally reluctant to have physicians accepting the bundled payments and paying hospitals their share. One solution to this is for the physicians and hospitals to create a joint Physician-Hospital Organization (PHO), controlled equally by the hospital and the physicians participating in the bundled payment; the PHO would accept the payment for the bundled services, and then allocate it between the hospital and physicians based on mutually agreeable rules. An alternative solution is what is known as "virtual bundling." In a virtual bundled payment, no one actually receives the combined payment; it is treated as a budget, and a payer divides it between the hospitals and physicians according to predetermined rules or an allocation agreed to by the hospital and physicians.

There is evidence that bundling of hospital and physician payments can be done successfully and produce better quality, lower cost care. For example, in the 1990s, Medicare's Participating Heart Bypass Center Demonstration selected four hospitals in Ann Arbor, Atlanta, Boston, and Columbus to receive a single payment covering both Part A (hospital) and Part B (physician) services for coronary artery bypass graft surgery. No outlier payments were permitted, and the amount of the combined payment was negotiated to be below current payment levels. The hospital and physicians were free to split the combined payment however they chose. An evaluation of the demonstration showed that the providers, patients, and Medicare all benefited: physicians identified ways to reduce length of stay and unnecessary hospital costs; costs decreased in nominal terms in 3 of 4 hospitals; and patients preferred the single copayment.[12] Beginning in 2009, Medicare began testing bundled payment on a broader range of conditions in its Acute Care Episode Demonstration, and preliminary indications are that the program has reduced costs for Medicare, improved margins for hospitals and physicians, and improved quality for patients.[13]

D. Providing an Inpatient Warranty

Today, under most current payment systems, both hospitals and physicians are paid extra to deal with errors or complications they themselves cause. For example, if a patient hospitalized for a medical condition develops an infection which leads to a longer stay in the hospital, the physician managing the case will likely be paid more than if the infection had not occurred, and the hospital will also likely be paid more, particularly if the infection causes significant complications.

Although it may sound desirable to pay for services patients need to address complications they experience in the hospital, this payment structure has the perverse effect of financially penalizing hospitals and physicians for efforts to prevent infections and complications in the hospital.

Medicare and other payers have tried to solve this by reducing or prohibiting additional payment for services associated with treating preventable errors or infections.[14] However, this approach only denies payment for treatment of the *error or infection itself*, not for any additional *complications* which may be caused by the error or infection, and the complications frequently result in far greater costs than the infection. Moreover, non-payment for a particular error or infection implicitly requires a judgment that that error or infection was fully preventable (otherwise, the provider is being penalized for a problem it could not control), which limits the number of errors and infections for which denial of payment is appropriate.

A better solution is for hospitals or physicians to offer a "limited warranty" as part of their care, i.e., they would commit that they would not charge more for addressing errors, infections, complications, etc. that occur during the patient's

care. The hospital and/or physicians offering the warranty would have to determine two things: (1) how broad the warranty would be, i.e., how many types of adverse events would be included, and (2) how much to charge for such a warranty. This flexibility is what distinguishes this approach from the more simplistic approach of non-payment for complications described in the previous paragraph – rather than a choice of either receiving full payment or no payment for costs associated with a specific complication, the hospital and physicians could define a price based on the extent to which they believe they can reduce such complications. More importantly, they then have an economic incentive to reduce the rate of complications even further.

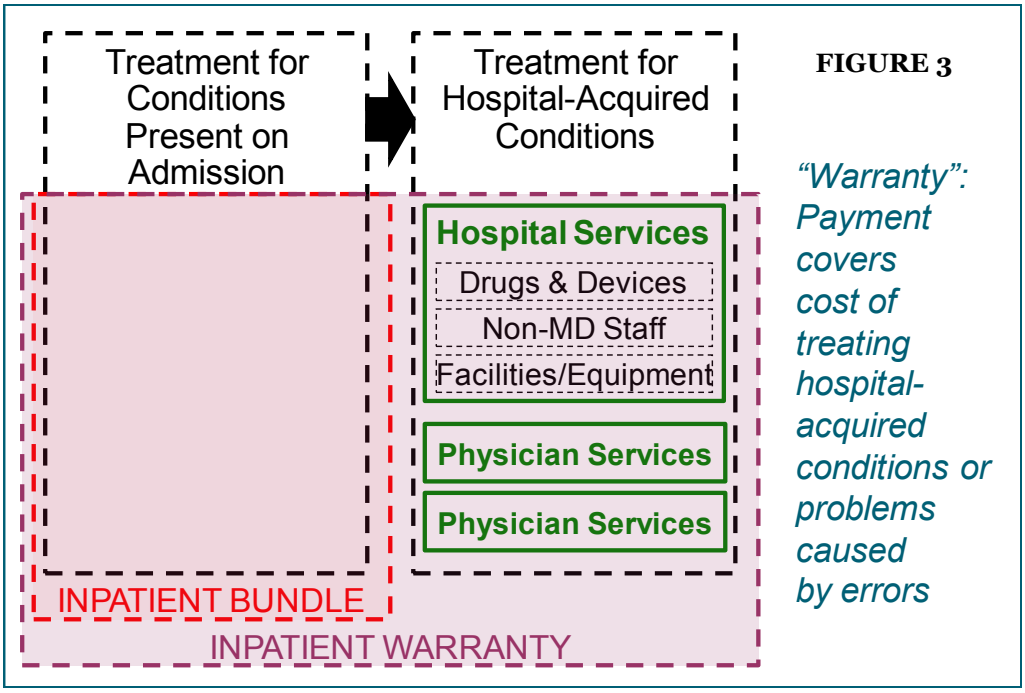

FIGURE 3

An example will help to illustrate this point. Suppose that today, a hospital is paid $10,000 for a certain procedure, but 5% of the time, patients get infections during their hospital stay; when an infection occurs, the additional payment for treating the complications is $20,000. The hospital believes it can reduce the rate of infections to at least 4%, so it begins offering the procedure with a warranty for infections, and it charges $10,800 for the warranted procedure. Although this price appears to be higher than the current payment of $10,000 for the procedure, it actually represents a savings for the payer, because the payer is currently paying an average of $11,000 for patients' care, given the current 5% infection rate ($11,000 = $10,000 + 5% x $20,000). If the hospital is able to reduce the infection rate to 3%, then it is still paid $10,800, but its costs are now below $10,600 ($10,000 + 3% x $20,000), so it is actually making more money. This approach is preferable to telling the hospital that it will not be paid any extra money for *any* of the infection cases, in which case the hospital would only be paid $10,000 for all cases and potentially lose money even if it reduced the infection rate significantly.

The pricing of warrantied payments may initially be confusing for many purchasers and payers, who will ask why they are paying *more* ($10,800 instead of $10,000 in the example above) for care when they are trying to save money. The answer is that they are not really paying the nominal price today; they are actually paying more per patient on average ($11,000 vs. $10,000 in the example above), but the additional payments are hidden in the costs of treating the errors and infections, and so paying more for care with a warranty will actually cost them less than paying lower prices multiple times. Outside of healthcare, people expect to pay more for products and services which have warranties than for those which do not.

Because there is a wide range of different types of infections and complications that occur in hospitals, and because there are varying degrees of knowledge about how to prevent them, it may initially be desirable to allow hospitals to compete on the breadth of their warranties, rather than trying to develop a uniform definition of a warranty. A disadvantage of this is that differences in the definitions of warranties make comparisons among providers more difficult, but this is similar to products and services in other industries which have warranties with varying lengths and exclusions. Over time, the definitions will likely converge as techniques for reducing infections and complications become more broadly implemented.

A hospital and its physicians could each separately offer such a warranty on their individual payments without having to bundle their payments together, i.e., this transitional step could be taken without taking the step described in Section II-C. However, it would likely be more challenging to successfully implement the warranties if the hospital and physicians were not both implementing them simultaneously so that their mutual incentives were aligned.

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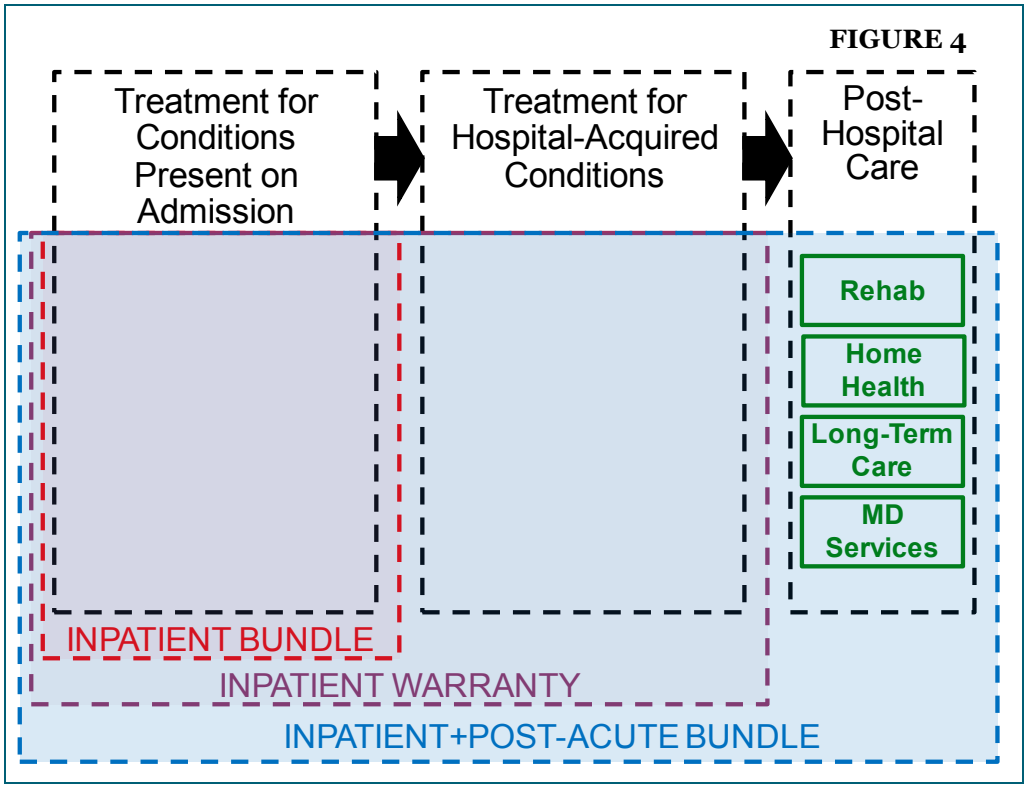
Although warranties sound like a radical idea, the Geisinger Health System in Pennsylvania, through its ProvenCare℠ system, has been providing a "warranty" on care for several years. The system was started for coronary artery bypass graft surgery, and has been expanded to hip replacement, cataract surgery, angioplasty, bariatrics, low back pain, perinatal care, and other areas.[15] Offering the warranty led to significant changes in the processes used to deliver care, and Geisinger has reported dramatic improvements on quality measures and outcomes.[16]

However, it is important to note that the ability to create warrantied payments is not limited to large health systems such as Geisinger. For example, in 1987, an orthopedic surgeon in Lansing, Michigan collaborated with his hospital to offer a fixed total price for surgical services for shoulder and knee problems, including a warranty for any subsequent services needed for a 2-year period, including repeat visits, imaging, rehospitalization, and additional surgery. A study found that the payer paid less and the surgeon received more revenue by reducing unnecessary services such as radiography and physical therapy and reducing complications and readmissions.[17]

E. Bundling Payments for Inpatient and Post-Acute Care

"Bundles" can be defined more broadly than just combining the hospital and physician payments for the services they provide during the inpatient stay. Many patients receive post-acute care services (e.g., home health care, rehabilitation services, etc.) after they are discharged from the hospital, and these are frequently delivered by providers unrelated to the hospital and physicians and are typically paid for separately. The fragmentation of payment can result in overuse or underuse of the post-acute care services as well as lack of coordination among all of the providers involved. One solution to this is to create a single, bundled payment for inpatient care and post-acute care services. (See Figure 4.)

Although many of the advantages and challenges of creating a single, bundled payment for inpatient and post-acute care services are similar to those described earlier in conjunction with bundling of hospital and physician services, a key difference here is that not all patients need post-acute care or need the same types of post-acute care. One patient may need physical therapy after a hospital stay, while another may not; one patient may have family members to help them recuperate following discharge and need no professional healthcare services, while another may need home health services or a temporary stay in a nursing facility to play that same role. Consequently, the price of the bundled payment cannot simply be the sum of the payment for an inpatient stay and the price of a post-acute rehabilitation stay or home health care. This means pricing the bundled payment has challenges similar to pricing a warranty – the provider accepting the bundle needs to estimate how frequently the various types of post-acute care will be needed, and then establish a price designed to cover post-acute care services at the necessary frequency.



There are other challenges to bundling inpatient and post-acute care besides pricing. In most communities, inpatient and post-acute care services are delivered by different organizations. Even if the health system that operates the hospital also provides post-acute care services, they are likely not the sole source of such services, and patients will want to have a choice

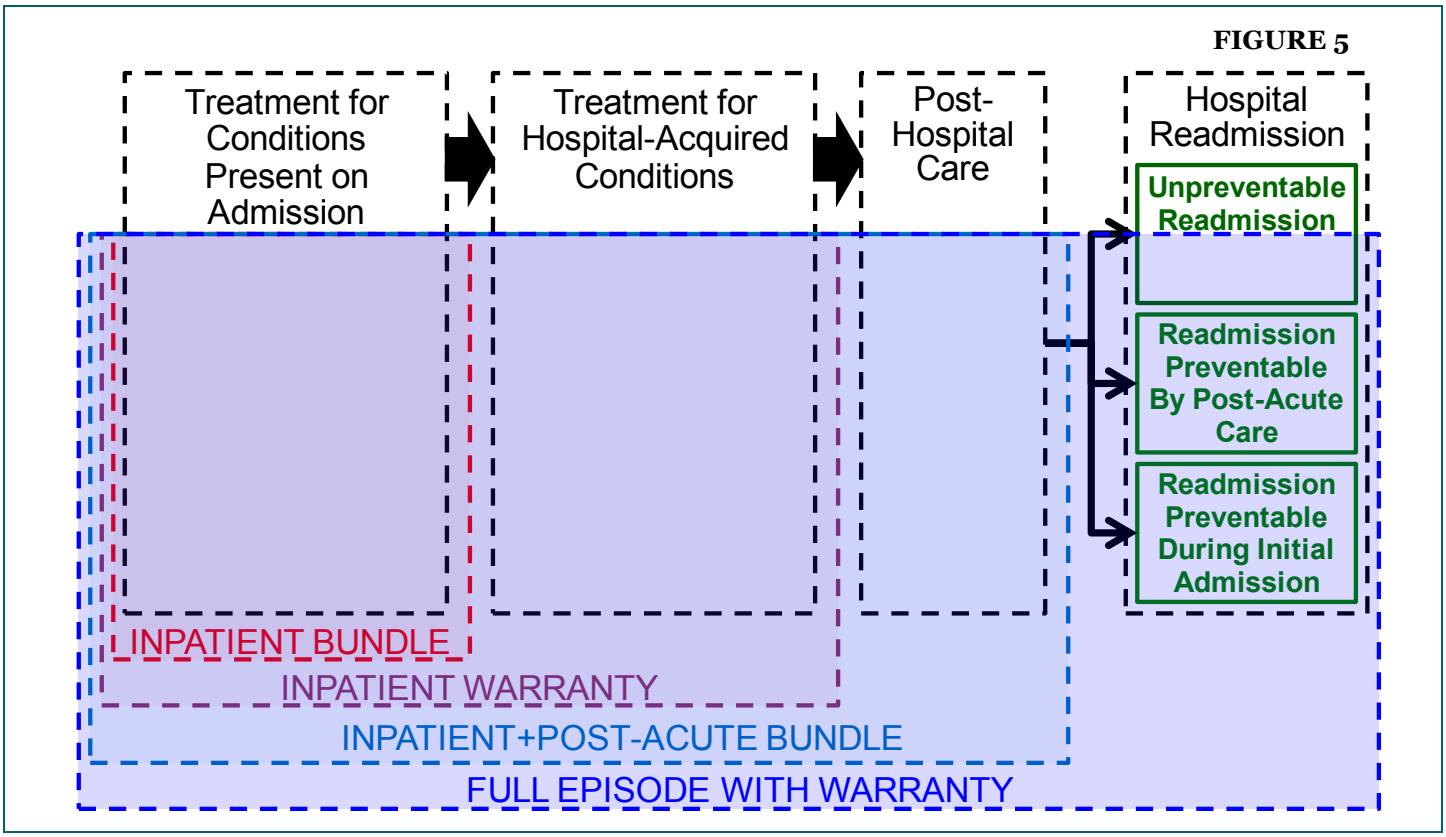
of which post-acute care provider they will use or they will be required by the payer to be given such a choice. In some cases, a patient may receive post-acute care services in a completely different community.

F. Providing a Warranty for Post-Discharge Complications and Readmissions

The warranty concept described in Section II-D for complications and adverse events that occur during the patient's hospital stay can also be applied to events that occur after discharge. In particular, there is growing concern about the high cost associated with patients who are readmitted to hospitals after discharge for treatment of conditions related to their initial admission.

Although a commonly-discussed approach is to reduce or prohibit additional payment to hospitals for services associated with readmissions, this approach requires making a judgment about which readmissions are fully preventable. If some readmissions are not preventable, then denying payment for them means denying payment for services that patients need, putting providers in the position of either refusing to provide the care or delivering the care without appropriate compensation. This is particularly a problem if a patient goes to a different hospital or physician for care during the readmission than the original admission.

A better solution is for the hospital and physicians to offer a warranty for post-discharge complications and readmissions. (See Figure 5.) As with the inpatient warranty, rather than giving the payer the simplistic choice of either making full payment or no payment for costs associated with a specific readmission, the hospital could define a price based on an expectation of reducing, but not necessarily eliminating, all of the readmissions. This allows the payer to pay less than it does today without penalizing the hospital for readmissions it cannot prevent, but retains an economic incentive for the hospital to continue working to reduce the rate of readmissions even further. Having the services of both hospitals and physicians included in the warrantied payment, particularly the physicians who will provide post-discharge care, is highly desirable because readmissions can be affected both by care in the hospital and care provided after discharge.



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G. Paying Based on Diagnosis Instead of Treatment

Today, even where case rates or bundled episode payments exist, they are frequently associated with a particular *procedure*. Although the hospital payment system used by Medicare and many other payers is based on what are called "Diagnosis" Related Groups, in reality, many of them are really "Treatment" Related Groups. For example, while MS-DRG 176 is defined in terms of a diagnosis of "pulmonary embolism without major complications," MS-DRG 234 is defined in terms of a specific procedure, "coronary bypass surgery with cardiac catheterization without major complications," rather than in term of the level of coronary artery blockage the patient is experiencing (i.e., the diagnosis).

On the surface, paying by procedure sounds like a fair way to compensate hospitals and physicians for the different costs of different types of procedures needed by two patients with the same diagnosis. The problem is that in situations where there are two alternative procedures which could be used to treat a patient with a particular condition, and where one of those procedures is paid at a significantly higher rate than the other, the hospital and physicians may make more money doing the more expensive procedure than the less expensive procedure. Conversely, if the hospital and physicians choose the less expensive procedure, it might save the payer money with no adverse effect on patient outcomes, but the hospital and physicians would see their revenues and profit margins decrease.

For example, one-third of pregnant women in the U.S. currently deliver by Cesarean section rather than vaginally, a rate which is widely believed to be much higher than necessary and which can result in poorer outcomes for both mothers and babies. Typically, payers pay two different amounts for vaginal delivery and Cesarean sections, with the latter payment being twice as high for hospitals and somewhat higher for physicians than the former; this creates undesirable financial penalties for hospitals and physicians which reduce the use of Cesarean sections.[18]

A solution to this is to move away from payments defined in terms of procedures to payments defined in terms of diagnoses. In the example above, creating a single payment for "labor and delivery of uncomplicated pregnancies," regardless of the delivery method used, would reverse the current financial penalty for reducing Cesarean sections and create a financial incentive as well as quality incentive to increase the rate of vaginal deliveries.

H. Targeting Payment Reforms to Facilitate the Transition

The transitional payment reforms described above need not be pursued in any particular sequence, as might be implied in Figures 1 through 5. For example, a hospital and physicians might choose to offer a warranty for post-discharge complications before they try to offer a warranty on inpatient complications, and a hospital might choose to define a bundled payment for inpatient and post-acute care services before it tries to define a bundled payment with its physicians. Moreover, different approaches can be used with different types of patients and conditions.

Indeed, one way to decide which transitional payment reform to use is to determine where the greatest opportunity exists for improving value. For example, as shown in Figure 6, if a hospital believes there are significant opportunities to reduce hospital-acquired infections or other inpatient complications, then it could work with payers to create an inpatient warranty so that it would no longer be penalized financially for reducing those infections or complications. It would not necessarily have to create a bundled payment with its physicians to do this, although doing so would provide an incentive for the hospital and physicians to collaborate on the strategy because both would be able to benefit financially from success.

However, what Figures 1 through 5 demonstrate is that once most or all of these changes are made for a particular procedure, the provider is then able to accept a complete Episode-of-Care payment for that procedure, i.e., a single payment that covers hospital services (Section II-A), all physician services (Sections II-B and II-C), all post-acute care (Section II-E), and any adverse events that occur during the inpatient stay (Section II-D) or after discharge (Section II-F). If these elements are combined for a particular diagnosis (Section II-G), then the provider is also able to accept a Condition-Specific Comprehensive Care Payment for that diagnosis (see Section III-D).

FIGURE 6

SELECTING A TRANSITIONAL PAYMENT APPROACH FOR MAJOR ACUTE CARE	
IF THE GOAL IS TO:	**USE THIS PAYMENT REFORM:**
Eliminate inpatient inefficiencies	Create case rates for hospital costs and for physician costs during inpatient stays (Sections II-A and II-B); Bundle hospital and physician payments during inpatient stays (Section II-C)
Reduce adverse events during inpatient care	Create an inpatient warranty, either for hospital costs or physician costs or both (Section II-D)
Encourage more efficient combinations of inpatient and post-acute care	Bundle inpatient and post-acute care payments (Section II-E)
Reduce readmissions and other post-discharge problems	Create a warranty for readmissions and post-discharge complications (Section II-F)
Shift treatment to lower-cost options	Define payments based on diagnosis rather than treatment (Section II-G)

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III. Payment Reforms to Support Accountable Medical Homes and Specialty Care

Although episode-of-care payment and the transitional steps described in the previous section have considerable promise for reducing costs and improving quality *within* major acute episodes, the major weakness of episode-of-care payments is that they do nothing to reduce the *number* of episodes. For many patients, such as individuals with chronic disease, the primary goal should not be to make their hospital stays better or cheaper, but to prevent hospital stays from being necessary in the first place.

Capitation payment or "global" payment systems attempt to address this problem by defining a single price for all services needed to care for a patient or a group of patients during a particular period of time, regardless of how many episodes of major acute care they receive.[19] A capitation/global payment makes several major changes from current payment systems:

- It combines payments for many services which are currently paid for separately into a single payment; and
- It makes one provider responsible for the costs of services delivered by a wide range of other providers, or makes a group of providers collectively responsible for the costs of the services they each deliver and for which they are currently paid separately;
- It makes the provider responsible for managing all of a patient's conditions, rather than just a subset.

Capitation/global payment is viewed as very challenging and risky for healthcare providers because it makes all of these changes at once, affecting many providers and many services in complex ways. However, as with episode-of-care payment, although all of these types of changes may be desirable, it is not essential that they all be made at the same time; indeed, one approach to transitioning to a full global payment system would be to make one or more of these changes without the others or to focus the changes on a subset of patients.

Three steps that could be taken by providers and payers to transition physician practices towards more global payment structures are:

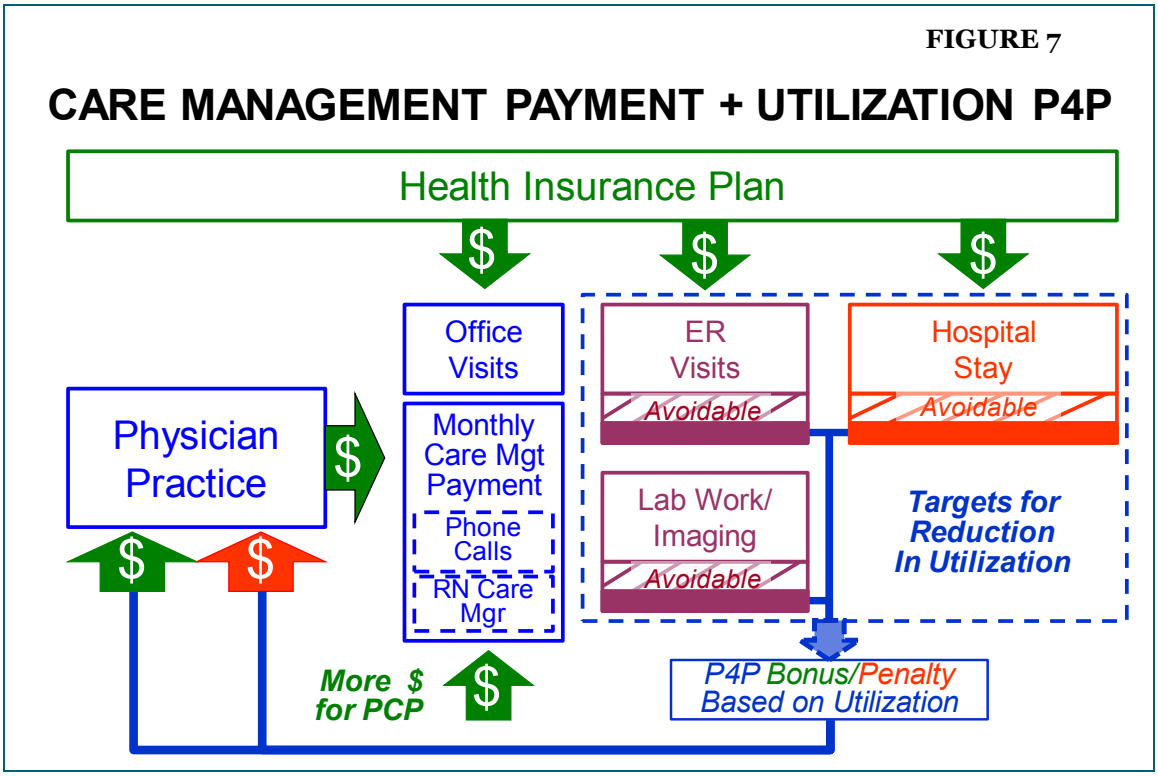
- Paying primary care practices Care Management Payments combined with utilization-based performance incentives;
- Paying specialists Care Management Payments combined with utilization-based performance incentives; and
- Paying physician practices or health systems Condition-Specific Partial Comprehensive Care Payments.

A. Care Management Payments and Utilization-Based Performance Incentives for Primary Care

As noted in Section I-B, a weakness of most current medical home payment models is that they increase payments to primary care practices to improve the way they deliver care without the practice accepting any accountability for ensuring that the improved care actually results in fewer preventable hospitalizations, fewer referrals to specialists, etc. A weakness of the shared savings payment model is that even though it rewards physician practices that reduce hospitalizations, it doesn't provide any upfront resources to enable the physician practices to improve the way they deliver care in order to reduce hospitalizations.

Rather than trying to choose between these two payment models, each with its own significant weaknesses, they could be viewed as complementary components that can be used as part of an incrementally better payment system for primary care practices. This would work as follows:

- **Component 1: Care Management Payment.** The primary care practice would continue to be paid at current fee levels for each individual service the practice delivers to any patient it sees, but in addition, a new Care Management Payment would be added to pay the practice for care management services (e.g., patient education and self-management support delivered by a nurse practitioner, access to physicians by telephone, etc.) to a group of patients (either all of the primary care practice's patients or a subset of patients who have specific diseases). The payment would be made on a per-patient basis, i.e., the practice would receive the payment regardless of what specific services it provides, or how many services are provided to any individual patient.[20]
- **Component 2: Targets for Utilization Reduction.** The physician practice would also agree to improve the way care is delivered to its patients so that the rates of utilization of specific healthcare services outside of the practice (e.g., non-urgent emergency room visits, ambulatory care sensitive hospitalizations, or high-tech diagnostic imaging) are below specific target levels. The target levels would be lower than current utilization rates, such that the reduction in utilization, multiplied by the amounts the payers pay for the services being reduced, would result in aggregate savings that are greater than the aggregate amount of payment made under Component 1.
- **Component 3: Bonuses/Penalties for Performance Against Targets.** A third component would be a pay-for-performance type of payment that would reward the practice for doing better than the targets and penalize it for failing to achieve the targets. The physician practice could receive a fixed bonus or "shared savings" payment for reducing utilization below the target level, but it would be required to refund all or a portion of the upfront care management payment if it failed to achieve the target level (with the amount of the refund being proportional to how far above the target the actual utilization for the patients was).



For example, suppose a four-physician primary care practice manages a total of 5,000 commercially-insured patients. These patients make 450 visits to emergency rooms each year for non-urgent reasons, at an average cost to their health insurance plan of $1000 per visit. The health plan agrees to give the practice a $2.00 monthly Care Management Payment for each patient to enable the practice to improve access to the practice for patients (e.g., longer office hours, weekend hours, and improved phone support). This represents $120,000 in additional revenues to the practice. The practice agrees that in return for the Care Management Payment, it will take accountability for reducing the rate of non-urgent ER visits by 30%. If it succeeds in doing this, the health plan will save more on ER visits ($135,000 = 30% x 450 x $1000) than the cost of the Care Management Payments. If the practice reduces non-urgent ER visits by more than 30%, the practice would receive a bonus payment from the health plan equal to one-half of the cost of the additional prevented ER visits, but if it fails to meet the 30% target reduction, it would be required to pay back a portion of the Care Management Payment equivalent to the cost of the extra ER visits.

A payment system with the above three components would be preferable to the current fee-for-service system, where the primary care practice receives no resources to help reduce emergency room visits, hospitalizations, etc., receives no financial penalty if they remain constant or increase, and receives no reward if ER visits or hospitalizations are reduced. But it would also be easier for a small practice to accept than a traditional capitation structure that would simply pay the

practice a fixed amount per patient, because even though such a payment would give the practice both the ability and incentive to reduce the rate of ER visits and hospitalizations, the practice would suffer a serious financial penalty if there was an unexpected increase in the rate of hospitalizations or the costs of hospitalizations for non-preventable reasons.

This middle-ground approach simulates the flexibility and accountability inherent in a capitation or global payment system, but limits both flexibility and accountability in ways that make it a more practical step for both the primary care practice and the payer. The Care Management Payment is both flexible and predictable, as a full global payment would be, and the utilization targets and bonuses/penalties give the practice incentives to manage utilization similar to what providers need to do to succeed under global payment arrangements.

The Care Management Payment in Component 1 is similar to the care management payments that many health plans are currently paying to primary care practices to help them become certified as "patient-centered medical homes."[21] However, most of these programs do not require that the medical homes accept any explicit accountability for reducing utilization of other services. They typically require that the medical home meet accreditation standards which are believed to increase the probability of reducing utilization, but which do not guarantee it. Consequently, many payers have been unwilling to pay a Care Management Payment of significant size because of the concern that this could simply increase the total cost of care. Components 2 and 3 address this concern by directly tying the increased payment to savings elsewhere.

A payer might understandably be concerned that basing targets and rewards/penalties solely on *specific services*, such as the rate of hospitalizations, rather than on *all services* to the patient runs the risk for the payer that the practice will utilize some other expensive services (e.g., increasing referrals to specialists) to reduce hospitalizations. However, if the primary care practice understands that this is a *transitional* payment system, and that targets for additional aspects of utilization will be phased in over time, then it would be undesirable for the practice to significantly increase the utilization of services that are unmeasured this year, only to have a bigger challenge of reducing them next year when those additional services are also being measured. In the meantime, giving the practice an easily understood and measured target to focus on initially would facilitate its ability to move toward more accountable care.

Setting targets based on *utilization of services*, rather than *total cost*, is also important, since it is reasonable to expect that a primary care practice can help manage patients' conditions in ways that avoid ER visits and hospitalizations, but it is not reasonable to expect that PCPs can control what happens once the patient is hospitalized, particularly when the hospital care is being managed by hospitalists or other physicians. Focusing on utilization avoids putting the practice at risk for the cost of hospital-acquired infections or price changes by hospitals or other providers that could wipe out any savings from reduced utilization.

B. Care Management Payments for Specialists

As with most current medical home payment programs, the above option only makes changes in payments and incentives for the primary care practice, not for the "medical neighborhood," i.e., the specialists and other providers who may also be providing services to the same patients. The Care Management Payment would provide flexible resources that could be used to compensate the primary care practice for contacting specialists to coordinate a patient's care, but it would do nothing to compensate the specialists for answering the primary care practice's call or for proactively contacting the PCP to coordinate a treatment plan.

To address this, a payment structure focused on specialists could be created with 3 components similar to those in Section III-A:

- **Component 1:** The specialty provider would receive a fee for consulting with a primary care practice about a patient's care (rather than only being paid for an office visit with the patient)[22];
- **Component 2:** The specialty provider would make a commitment to work with the primary care practice to achieve specific targets for reduction of avoidable hospitalizations and ER visits, duplicative testing, etc.; and
- **Component 3:** A bonus/penalty payment would be established so that the specialist would be rewarded if the joint effort with the primary care practice beat the targets in Component 2, but the specialist would have to refund a portion of the new fees if the targets were not met.

Here again, this transitional approach simulates the flexibility and accountability of a global payment system, since under a global payment system, a specialty provider can be paid more or differently if they are helping to reduce overall costs.

C. Condition-Specific Partial Comprehensive Care Payment

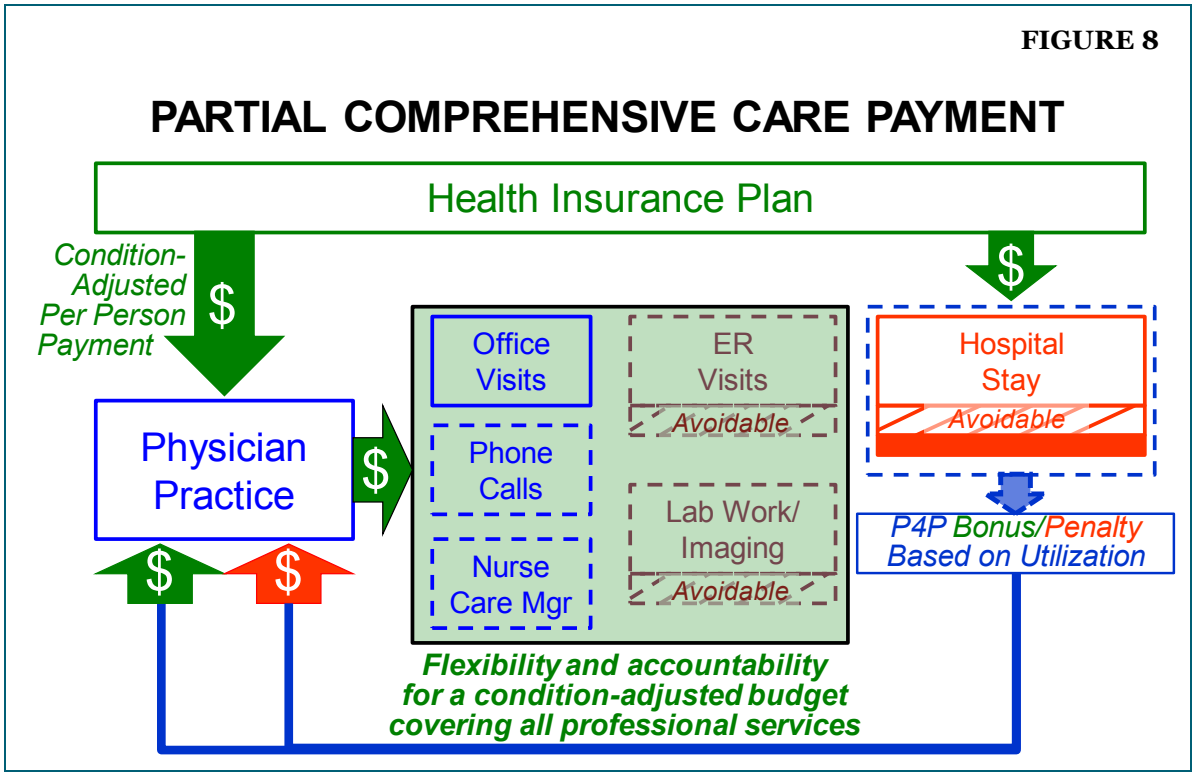
A third transitional approach is to pay a physician practice, an Independent Practice Association, a health system, or other provider or group of providers a single amount for most or all of the services that a patient will need from most or all providers for one or more of the patient's health conditions over a fixed period of time (e.g., a year). This "Condition-Specific Partial Comprehensive Care Payment" would replace separate fees currently paid for the services that are covered by the payment.

1. Services to be Included in the Payment

A range of different types of services could be included in such a payment depending on the provider's willingness and ability to take responsibility for those services:

- **The Provider's Own Services.** At one extreme, the services could be limited only to those which are currently delivered by the provider receiving the payment. For example, a primary care practice might receive a single payment to cover the costs of all of the services it currently provides to its patients (in place of the fees it is receiving today), but not for any costs delivered by other providers (i.e., specialists, hospitals, etc. would still be paid as they are today). A version of this approach that has been used by some payers is "practice capitation," in which the physician practice receives a single per-patient ("per capita") payment to cover all of the services the practice provides to the patient, but services delivered outside of the practice are still paid separately. A growing number of primary care practices, particularly those describing themselves as "concierge" practices, have instituted a similar approach in the form of prepaid annual fees for self-pay consumers.

  This type of payment gives the provider complete flexibility about what services to offer and how to target services to the patients who need them the most. However, unless there are other cost and quality incentives included in the payment structure, this approach can also diminish the provider's incentive to deliver services at all, since the provider is paid regardless of how many services it provides to the patients, as long as the patients remain associated with that provider, and it has a financial incentive to refer patients to other providers to receive services (since they would still be paid separately for delivering those services) rather than having the provider



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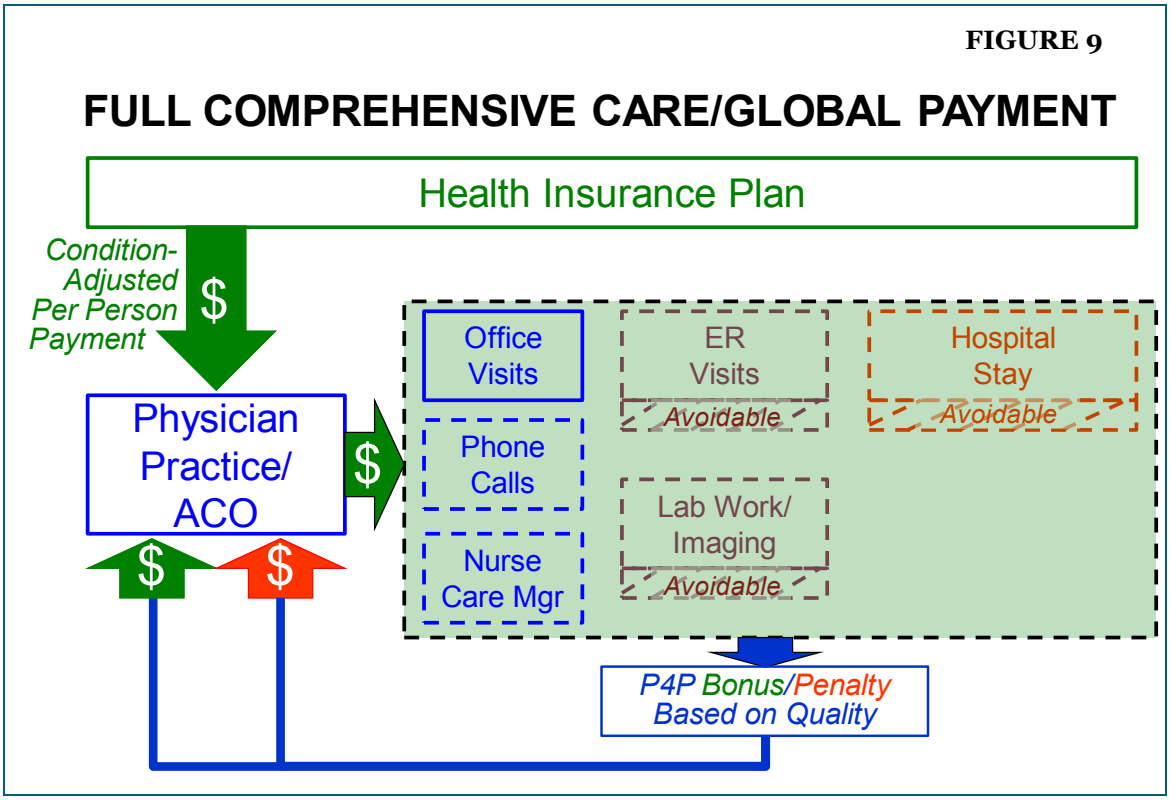
receiving the Comprehensive Care Payment delivering those services directly. (This could be addressed by adding utilization targets and quality payment bonuses/penalties, similar to Components 1 and 2 that are described in Section III-A.[23])

- **Some Services Offered by Other Providers.** A more advanced option is to include in the payment to a provider the costs of *some* services that *other* providers deliver; these should be costs that the provider who receives the payment can influence or control. For example, a primary care practice might receive a payment that covers not only the services it delivers, but also the costs of diagnostic imaging services or emergency room visits for its patients. This would create an incentive for the primary care practice to limit excessive use of the imaging services or emergency room, since it could keep any savings, and it would also give the practice the flexibility to substitute other services (e.g., using physical therapy instead of an MRI for a patient with back pain, holding weekend office hours to deal with urgent issues rather than sending patients to the ER, etc.). However, it would also require the practice to actively manage the patients, since it would be liable for the costs of the included services any time the patient received them.

  A version of this approach that payers in some parts of the country use to pay physician practices is known as "professional services capitation," i.e., a single payment that covers the costs of all services delivered by physicians and other healthcare professionals, but not hospital costs. This provides great flexibility to determine exactly what services a patient needs, and a significant incentive to reduce unnecessary referrals and services, including hospitalizations (since a hospitalization will involve considerable professional services fees), without putting the physician practice at risk for the large total costs of hospitalizations. (A pay-for-performance component could also be included based on the utilization of the hospital.)

- **Most Services Offered by Other Providers.** The most advanced option would be to include in a single payment most or all of the costs of most or all services that all providers would deliver, including most hospitalizations. This would be similar to traditional full capitation contracts, except that the payments would be risk-adjusted and risk-limited in specific ways (see Section IV). A narrow set of specific services might still be excluded, particularly those that occur infrequently and involve large costs, since these are least likely to be controlled by a provider who does not directly offer the services. In addition, limits on the total amount of costs that the provider would be responsible for, either on a per patient or per case basis, would help to avoid providers taking on too much risk for all services (ways to limit provider risk are described in more detail in Section IV-B).[24]



2. Patient Conditions to be Covered by the Payment

A key difference between Condition-Specific Partial Comprehensive Care Payment and full capitation or global payment is that the Condition-Specific Partial Comprehensive Care Payment would be targeted to specific types of patients or a subset of their conditions. For example, suppose a physician practice felt that it could manage the overall costs of treating diabetics for their diabetes-related problems, but it was not yet prepared to do so for any other patient population or for issues unrelated to the diabetes. It could agree to accept a Condition-Specific Comprehensive Care Payment for patients with diabetes, but continue to receive traditional fee-for-service payments for all other patients, and also for other unrelated conditions or problems the diabetic patients experience (treating injuries from an accident, for example).[25]

For example, the PROMETHEUS payment system has defined a risk-adjusted payment amount to cover all of the care needed during the course of a year by a patient with a specific chronic disease. The payment is intended to give providers adequate resources to manage the care of the patient in a high-quality way, as well as a financial incentive to reduce preventable hospitalizations and other avoidable complications. This payment model is being tested in several pilot sites.[26]

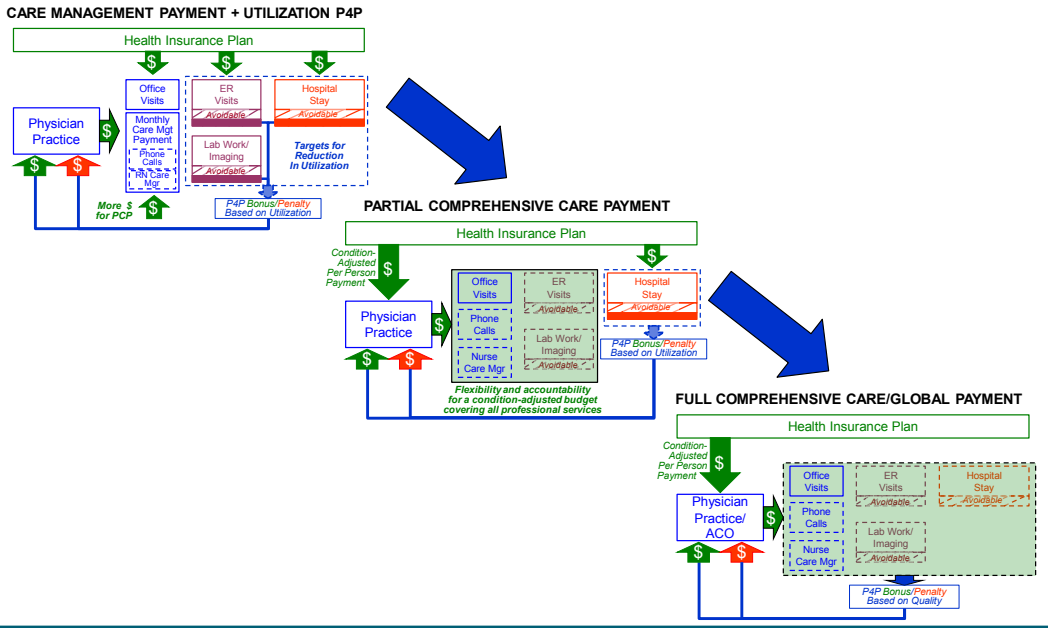
D. Moving From Condition-Specific Payment to Global Payment

Although Condition-Specific Comprehensive Care Payments may sound far more narrow and feasible to manage than a full capitation or global payment system, a global payment system that is risk-adjusted can be thought of as simply the aggregation of a series of condition-specific payments. For example, if a provider receives a global payment to manage a group of patients, some of whom have diabetes, some of whom have congestive heart failure, and some of whom have both conditions, and if the global payment amount is adjusted up or down based on the number of patients in each category, then this "condition-*adjusted* payment" is technically equivalent to the provider receiving a condition-*specific* payment for the patients with diabetes, a separate condition-specific payment (with a different price) for the patients with congestive heart failure, a third condition-specific payment (with yet a different price) for the patients with both diabetes and congestive heart failure, and a fourth condition-specific payment for the patients with neither condition.

This means that providers can use condition-*specific* payments to make the transition to condition-adjusted global payments, focusing initially on individual types of patients with particular combinations of conditions, learning how to manage the costs and quality for certain services for those patients, and then adding new services and new groups of patients over time until the full range of patients and the services they need can be managed effectively, at which point the provider is capable of accepting a condition-adjusted global payment in place of the collection of individual condition-specific payments.

FIGURE 10

TRANSITIONING TO ACCOUNTABLE CARE PAYMENT



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IV. Setting Prices, Managing Risk, and Ensuring Quality

For any of the transitional payment reform steps defined in previous sections, as well as for full global payment or episode-of-care payment systems, three additional issues must be addressed:

- Establishing an appropriate payment amount (i.e., a price) for each patient or group of patients;
- Limiting the financial risk associated with unusually expensive patients or with costs that the provider cannot control; and
- Ensuring that the quality of care to patients is maintained or improved as incentives to control costs are introduced.

A. Setting Prices

Sections II and III focused on how to change the *method* of payment for providers in order to improve their ability and incentive to reduce overall costs and improve the quality of healthcare. However, under any payment method, the payment *level* is also critical. Even if the payment method provides the right incentives, if the payment level is too low (i.e., below the minimum feasible cost of providing care), providers will be unable to provide quality care, and if the payment level is too high, there will be no real incentive for efficiency.

Why Price-Setting is Difficult

There are three principal reasons why it will be difficult, particularly initially, to set appropriate prices for care under new payment methods:

1. Bundled payments and payments with warranties require substituting a single payment for what were previously separate payments for a varying number of services. In certain cases (e.g., surgery), where there is already a single payment for one set of services (those delivered by the hospital) and a single payment for another set of services (those delivered by the surgeon), and where *all* patients receive *both* sets of services, it is a simple matter to add the two payments together to define the single combined payment. In most cases, however, there is significant variation in the number of services provided, the number of different providers involved, etc., and so defining a single payment for a particular type of patient or procedure requires determining what the appropriate "average" level of services should be. Although some of the current variation in the types and frequency of services is likely to be inappropriate, some of the variation reflects legitimate differences in patient needs, and so the challenge will be determining the proper balance. Having a good condition/severity adjustment system (see Section IV-B) will help, because there should be less variation for more homogeneous groups of patients.
2. It is widely recognized that current prices for many individual services differ significantly from the costs of delivering those services.[27] This means that even if one can determine the "right" combination and frequency of services within a bundle or the feasible level of errors, complications, etc. for a warranty, the price of the bundle or warranty will still be wrong if it is based on the current prices of the services being bundled or warrantied. Even prices which are "right" today may not accurately reflect what costs will be in the future for many services which will be utilized less frequently, since a provider's fixed costs will have to be spread over a smaller volume of services. This will be an issue particularly for providers like hospitals with high levels of fixed costs that have long amortization periods (e.g., facilities and major equipment).[28]
3. In many cases, the actual prices paid for services are a closely guarded secret, and so it is difficult for a provider to determine the actual prices for services delivered by other providers if both are to be included in a new, combined payment amount. Moreover, the prices paid for services vary significantly from provider to provider, so in addition to the variation in the number and types of services similar patients receive today (as described in #1, above), there will be variation in prices depending on which other providers are used, both variations based on genuine differences in the costs of delivery and variations driven solely by the relative negotiating power of the providers and payers.

It is important to note that having "bundled" payment systems will not eliminate the need to have accurate prices for individual providers and services. As long as there are separately incorporated providers involved in the delivery of care, some mechanism of dividing up the episode or comprehensive care payment among them will be needed, and that will require prices (or the equivalent of prices) for each of the providers' individual contributions as well as for the combined package of services. However, these internal prices will only be used by the providers themselves to allocate their costs, and there will be no need for either payers or patients to know what they are or how they are determined.

The Need for Data to Set Prices

In order to address the above challenges, it is critical to have current data on utilization and costs of services. For example:

- setting a price for a bundled payment of care requires knowing what services are currently being delivered during such episodes by which providers at what price, and gaining support for the bundled price from the participating providers requires showing them how their share of the bundled payment is going to compare to the payments they currently receive.
- pricing a warranty requires knowing the frequency with which adverse events (such as infections, complications, re-admissions, etc.) occur.
- defining comprehensive care payments requires knowing the rate at which patients receive services from providers which are not part of the organization that will be managing the payment (i.e., "out-of-network" providers) and the payment amounts for those services.

In general, these data are not readily available to providers today, particularly those which are not part of a large, integrated delivery system. Indeed, to a significant extent, many of the quality and cost problems in healthcare today exist because healthcare providers do not have access to the kinds of information that will tell them whether or not problems exist, if the problems are improving or worsening, or even if the solutions are being implemented as intended.

MANY OF THE QUALITY AND COST PROBLEMS IN HEALTHCARE TODAY EXIST BECAUSE HEALTHCARE PROVIDERS DO NOT HAVE ACCESS TO INFORMATION THAT WILL TELL THEM WHETHER OR NOT PROBLEMS EXIST OR IF THE PROBLEMS ARE IMPROVING OR WORSENING

Unfortunately, the large investments currently being made in installing Electronic Health Records (EHRs) will likely do little to solve this. EHRs are primarily designed to retrieve information about individual patients, not to analyze patterns of care across multiple patients. Moreover, an EHR will only contain information about the services delivered by the providers who use that particular EHR; information about services delivered by other providers will only be available if they have a compatible EHR and a mechanism for sharing data between the two.

The most likely source of information to help providers establish appropriate prices will be multi-payer databases that have been established by states and by Regional Health Improvement Collaboratives.[29] Although most of these databases are currently being used primarily to produce measures of the quality of physicians' and hospitals' care, they can increasingly serve as a powerful tool for helping providers identify cost-saving opportunities and develop the business case for care changes to capture those opportunities.

Alternative Approaches to Price-Setting

The way the decision is made about the actual payment level and who makes that decision will depend on the overall mechanism used for price-setting for specific payers in a particular healthcare market. There are four different approaches to price-setting used in healthcare today:

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- **Regulation,** i.e., the government defines the price that a provider can charge or be paid. For example, the Maryland Health Services Cost Review Commission sets all-payer prices for hospital services in Maryland.
- **Price-Setting by Large Payers**, i.e., large payers define the amounts they will pay specific types of providers in a particular market. For example, Congress and the Centers for Medicare and Medicaid Services (CMS) establish detailed rules defining the rates that Medicare will pay providers.
- **Negotiation**, i.e., individual payers negotiate with individual providers to determine prices. This is the most common way of setting the prices paid to providers by commercial health insurance plans in most markets, and the outcome depends on the relative bargaining power of the payers and providers.
- **Competition by Providers**, i.e., providers set prices themselves and patients choose providers based on price as well as quality. The ability to do this depends on whether the benefit design in the patients' health plan makes them responsible for paying for differences in prices, as well as the availability of multiple providers for patients to choose among.

At one extreme, where prices are set by regulation or by a payer that has little or no competition (such as Medicare), it is likely that the same price will be used for all providers, or that differences will be based on objective factors for differences in costs that are unrelated to practice variations (for example, Medicare pays providers more only if they are teaching facilities, located in higher cost-of-living regions, etc.) This puts the burden on the regulator or large payer to determine what price is appropriate, and providers have a strong incentive to push for higher prices rather than to lower costs.

Where prices are negotiated, it is common for different prices to be paid to different providers for the same services based on the relative market power of the providers as well as objective reasons for differences in cost. This creates incentives for providers to consolidate, which can create greater inefficiencies as well as enable demands for higher prices.

In cases where patients pay all or part of the differences in prices between providers, providers can set different prices themselves and let the market determine whether there is sufficient difference in quality to justify a difference in price. However, the ability to do this depends on having multiple providers offering similar services and having the capacity to accept additional patients, and it also depends on having easy-to-understand information on the quality of services so that patients' choices are made on value (i.e., quality and costs) rather than costs alone.

B. Limiting Financial Risk for Providers

Even with the best data, the challenges described in the previous section mean that it will likely be impossible to get the prices under any new payment methods exactly "right," particularly during the transition process. Providers will get better at accurately pricing bundles and warranties once they have more experience implementing them, but in the short run, there will be financial risk for a provider if prices are set too low and financial risk for payers if prices are set too high. In order to avoid having this risk deter implementation, transitional payment systems will need to have ways of limiting this risk.

1. Condition/Severity Adjustment

Healthcare providers generally have little or no control over whether a patient will have serious or major health conditions such as cancer, head trauma, pregnancy, etc. The fact that some patients need more services, and therefore incur higher healthcare costs, because they have more health conditions or more severe conditions is known as "insurance risk." Conversely, once a patient has a particular set of health conditions, healthcare providers have the ability to control how many and what types of services the patient will receive to treat those conditions, and therefore providers (not payers) have the most direct influence on the quality and cost of care for any given combination of conditions. Consequently, a good payment system will keep as much insurance risk (the risk of whether a patient has an illness or other condition requiring care) as possible with the payer (Medicare, Medicaid, or an insurance company), and transfer as much "performance risk" (the risk of whether a condition can be treated successfully for a specific amount of money) as possible to physicians and other providers.[30]

A key method for separating insurance risk and performance risk is the use of a condition/severity-adjustment system.[31] If one patient has more health conditions or more severe conditions than another, the amount the provider is paid

for delivering any particular combination or bundle of services to the first patient is "condition/severity-adjusted" to be higher than the amount paid for the same combination or bundle of services to the healthier patient. Defining a more homogeneous group of patients for which a single payment is made also makes it easier to establish an appropriate price for the services needed to treat the patients with those characteristics.

Similarly, if the payment system includes a bonus or penalty structure, then it is important that a provider's bonus or penalty be based on its performance on factors it can control, not on differences in the types and severity of conditions that the provider's patients have, so condition/severity adjustment is important here, too. In addition, adjustments may be needed for factors other than health conditions; for example, patients with language barriers, low income, or other socio-economic challenges can require more intensive and expensive assistance in managing their health conditions.

In theory, the more condition adjustment factors that are used, the more providers can be protected from insurance risk, and the more precisely payment can be matched to the actual cost of services.[32] However, there is no hard line distinguishing where insurance risk ends and performance risk begins. One patient may be harder to treat than another for the same condition or may have adverse reactions to treatment due to unmeasurable factors that are outside the control of a physician, making it difficult to say how much of the higher costs of treatment are due to insurance risk vs. performance risk. Similarly, through good preventive care, a healthcare provider can reduce the likelihood that patients will develop conditions or can identify conditions in an earlier stage where treatment costs are lower, so providers can impact what otherwise would be considered insurance risk.[33]

Condition/severity-adjustment systems can evolve over time as a better understanding is developed of the factors affecting the need for services. For example, beginning in October, 2007, the federal Medicare program changed the condition/severity-adjustment system used in its hospital DRG payment system to ensure that hospital payments more appropriately reflected differences in patients' needs for services.[34] Similarly, Medicare added a condition/severity adjustment system to the way it paid Medicare Advantage plans in 2000, and then introduced a new and improved system beginning in 2004.

2. Outlier Adjustments and Risk Corridors

Because of the inherent limitations on condition/severity-adjustment systems, when the provider accepts a fixed payment for a group of patients, even if it is adjusted based on their actual health conditions, that provider still incurs a risk that one or more patients will need many more services or unusually expensive services than the payment covers, without a sufficient number of patients needing fewer services or lower-cost services to offset the higher-cost patients. The risk is much lower than if there were no condition/severity-adjustment at all, but it cannot be eliminated completely[35]. The problem is exacerbated for small providers, since a single unusually expensive patient will represent a much larger proportion of the provider's overall costs of caring for the group of patients. To mitigate this, payment systems can incorporate provisions designed to protect providers (and also payers) against such situations.

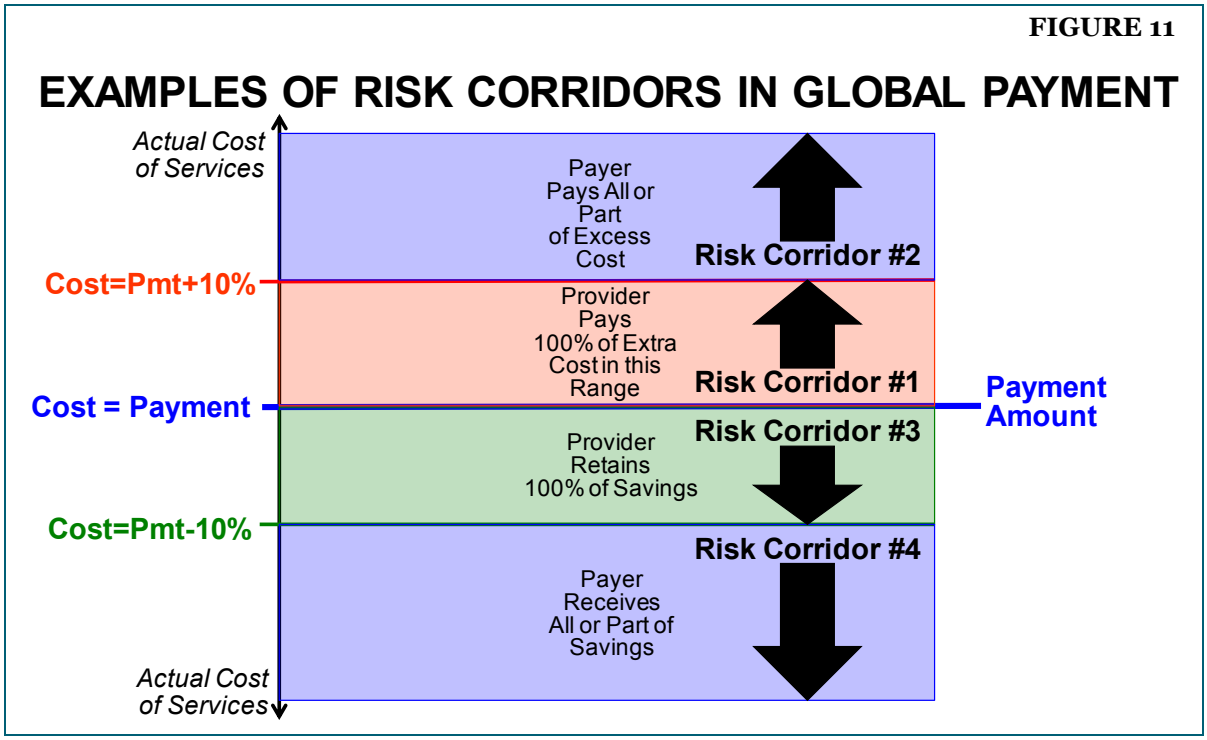
Outlier Adjustments/Reinsurance

One commonly used approach is to make an additional payment or some other form of payment adjustment (e.g., an adjustment to the calculation of a bonus payment or penalty) to a physician for a patient who has rare or unexpected problems that require an unusually large number of services or unusually expensive services, or who poses unusual challenges to the physician's ability to meet quality performance standards. Since these patients are "outliers" in the typical distribution of services and costs, the adjustment is known as an "outlier payment" or (in the case of bonus/penalty calculations) "outlier adjustment." Typically, an outlier payment is made when the total costs of services exceed some threshold or multiple of the payment level.[36] An alternative to making outlier payments is to require the provider to purchase reinsurance, i.e., an insurance policy that pays the provider if a patient's care is unusually expensive. Outlier adjustments typically involve excluding the unusual patient from calculations of total cost or quality performance when determining bonus or penalty payments, or limiting the total amount of cost that such a patient will contribute to a calculation of costs or savings.

Risk Corridors

Another approach is to measure the extent to which actual costs exceed payment levels for a *group* of patients. Instead of or in addition to making an outlier payment for an *individual* patient if the cost of services for that one patient

exceeds a certain threshold, a payer could make an additional payment if the average costs of *all similar cases* exceed a predetermined threshold. For example, if the average cost of treating all patients who have pneumonia exceeded 110% of the amount the provider is paid for treatment of pneumonia patients, the provider might be expected to cover the excess cost up to 10% of the total payment amount (i.e., to spend 110% of the payment amount to care for the patients) and then be given an extra payment to cover all or part of the portion of the costs beyond 110% of the total payment for all of the patients treated. This is known as a "risk corridor;" in this example, when costs are between 100% and 110% of the payment amount (i.e., they are in "risk corridor #1"), the provider takes full responsibility (i.e., accepts full risk) for paying those costs even though they are greater than the payment amount, but when actual costs are above 110% of the payment amount (i.e., in risk corridor #2), the payer accepts a portion of that risk and pays an additional amount to cover all or part of the costs that exceed 110% of the base payment. The advantage for a payer of using risk corridors is that it avoids having to pay more for one unusually expensive case if the provider has managed to keep its costs for other patients well below the payment level and could offset the extra costs itself.



Risk corridors can be defined in the other direction as well, i.e., if it turns out that a provider can treat a group of patients at significantly *lower* cost than the payment amount, the payer may want to share in those savings. So, for example, if costs are between 90% and 100% of the payment amount (i.e., in risk corridor #3), the provider might keep the full savings (i.e., bear the full "risk" of achieving savings), but if the costs are below 90% of the payment amount (in risk corridor #4), the payer could require that it receive a rebate of all or a portion of the difference between the actual costs and 90% of the payment.

The potential magnitude of the risk depends on the nature of the services that the provider has accepted accountability for. If the services are individually very low cost, then even if the provider has patients who need an unusually large number of services, the cost impact will be much lower than if some of the services are very high cost and the provider has patients who need an unusually large number of the high-cost services. For example, if a physician practice has agreed to provide as many *practice-based* services as a group of diabetic patients need for their diabetes in return for a fixed payment, the practice could have a patient that requires many visits, or extra-long visits, but the cost of those extra services to the practice would be relatively small. On the other hand, if the practice has agreed to provide or arrange for *any* services that the diabetic patients need for their diabetes in return for a fixed payment, the practice could experience a very high cost if several of the diabetic patients require (for example) amputations as a result of their diabetes.

Since most current payment systems give very little risk in either the insurance or performance risk categories to providers, even if all insurance risk is retained by the payer, many providers will not be prepared to accept full performance risk immediately, particularly for a broad range of patients and services, and particularly for high-cost services such as hospitalizations. Consequently, it would be desirable to phase in risk corridors over time; e.g., initially, a provider might only be liable for costs that exceed payments by 5% and only eligible to keep savings up to 5% of the payment

amount, but later, the provider might accept liability for costs that exceed payments by 10% or 15%, and in turn have the ability to keep an even larger share of savings.[37] Similarly, different risk corridors can be defined for providers of different sizes, so that small providers could receive greater protection against unexpected expenses, particularly in the early stages of their transition to accepting greater accountability for costs.

3. Exclusions and Risk-Sharing

Healthcare providers are far more likely to be willing to accept responsibility for the utilization and cost of services they deliver themselves than those delivered by other providers, particularly if they do not have a good working relationship with those other providers or if they believe the other provider is not committed to controlling costs or improving quality. Although many people believe that the solution to this is to have a full range of providers owned by the same corporate entity, corporate integration does not guarantee clinical integration, and moreover, unless the integrated provider is the *only* provider in the community, there is no guarantee that a patient who uses one service from that integrated system will obtain *all* of their services from that system. Indeed, the Medicare fee-for-service program and the majority of commercial health plans do not restrict patients to a single provider or group of providers. In most communities, certain services will only be obtainable from a single provider in the community (e.g., there may be only one hospital which does major organ transplants), and other providers may be reluctant to accept responsibility for the utilization or costs of services delivered by that provider when a patient needs them. There will also be situations in which a patient is unable to receive any services from the accountable provider for some period of time; for example, individuals who spend part of the year living in a different part of the country, or who develop health problems while traveling will have to receive their healthcare services from other providers during those times.

Excluding Certain Services or Cost Drivers from a Bundled or Comprehensive Care Payment

The techniques of risk adjustment, outlier payments, and risk corridors described in the previous sections do not effectively address this issue. The provider may be willing to take full accountability/risk for all of the services that it delivers directly, but no accountability or only partial accountability for the services delivered by certain other providers. Consequently, the payment model can be designed to exclude or "carve out" certain services, e.g., the payer would continue to pay for the excluded services on a fee-for-service basis, while paying for non-excluded services through a bundled or comprehensive care payment. In some cases, a provider may be willing to take accountability for whether a patient uses a service delivered by an outside provider, but not for the price of those services if the outside provider is in a position to negotiate high prices or increases in prices; this can be addressed by making the accountable provider responsible for increases in the *utilization* of the outside provider, but not for increases in the *price* of that other provider's services.

The challenge is to define the exclusions in a way that preclude or limit the potential for the accountable provider to inappropriately shift patient care to the excluded categories, particularly in cases where the patient would have higher-than-average costs if they received care from the accountable provider.

Sharing Risk Among Providers

An alternative option for limiting a provider's financial risk for the costs of services delivered by another provider is to formally transfer accountability to the other provider through a formal contract between the providers. The second provider might be asked to agree to provide a specific group of services for a fixed price per patient (which makes the first provider responsible for controlling how *often* the second provider is utilized, but not for how *many* services the second provider delivers when it is utilized for a particular case), or to make that group of services available to all of the first provider's patients for a fixed budget based on the total number of patients the first provider is managing (regardless of how many of the patients actually use the second provider or how often they use them).[38] For example, a physician practice would likely be more willing to accept a full Comprehensive Care Payment (as described in Section III) if the local hospitals were all offering warrantied, bundled payments (using the techniques described in Section II) for the major categories of hospitalizations; this would enable the physician practice to focus on managing patient care so that their patients are hospitalized less frequently, while knowing with certainty how much it would cost if the patients were hospitalized, and the hospital and specialists could focus on how to ensure that the hospitalizations that do occur have the lowest cost and highest quality possible.

C. Ensuring the Quality of Care

A common concern about payment reforms that are designed to increase incentives for providers to *control costs* is that they will also create incentives for providers to *withhold care* that patients need or to deliver *lower-quality care* in order to reduce costs. For example, capitation payment systems have been criticized because the provider is paid the same amount regardless of how much care a patient receives, which gives the provider a financial incentive to deliver no care at all.

It is important to recognize, however, that even fee-for-service payment, with its inherent incentives to deliver more services to patients, does not guarantee the delivery of higher quality care, as evidenced by the proliferation of quality-based pay-for-performance components in commercial fee-for-service payment systems. Indeed, in fee-for-service payment, the incentive swings too far in the other direction, since a provider receives more revenue for treating infections, complications, and other conditions that might have been prevented with better quality care.

The fact is that no payment system will, in and of itself, *guarantee* higher quality care unless higher quality care is explicitly rewarded and/or lower quality care is explicitly penalized in the payment system. In order to achieve higher-quality, lower-cost healthcare, the payment system must explicitly enable and reward both types of outcomes. (In addition to using the payment system to encourage higher-quality, lower-cost care, it is also important that the design of a patient's health benefit plan should give the patient incentives to choose higher quality, lower-cost providers and services.)

SINCE DIFFERENT PAYMENT SYSTEMS CREATE DIFFERENT KINDS OF INCENTIVES AND DISINCENTIVES, NO SINGLE SET OF QUALITY MEASURES AND PAYMENT ADJUSTMENTS WILL BE APPROPRIATE FOR ALL PAYMENT REFORMS

However, since different payment systems create different kinds of quality incentives and disincentives, no single set of quality measures and payment adjustments will be appropriate for all payment reforms. For example, if a provider accepts a payment with a warranty for errors, infections, or complications occurring during treatment, there is no need to have a separate quality bonus/penalty for such errors, infections, and complications, because there is a built-in penalty for the provider if such events occur, namely, it has to correct the problems with no additional compensation. In the absence of such a warranty, however, a separate bonus/penalty component would need to be added to the payment system to provide similar incentives.

As payment reforms along the lines described in Sections II and III are developed and implemented, they will need to be accompanied by *appropriate* quality incentives to address three principal categories of quality problems:

- Poor quality in a service that results in patient problems requiring treatment that is not included within the overall scope of services covered by the payment for that service. In the example above, if treatment for an infection that occurs during a procedure is *not included* in the payment for that procedure, then a separate system would be needed to reward or penalize the providers delivering that procedure based on the rate at which infections occur. However, if treatment for the infection is *included* in the payment, there is *no need* for a separate reward or penalty. (Patients and payers may still want to know how often infections occur, but reporting quality measures does not mean that payment needs to be explicitly tied to them.)
- Poor quality in a service that results in patient problems occurring outside the timeframe covered by the payment for that service. To continue the above example, if the provider gives a warranty for infections occurring *within* 7 days of a procedure, it may be necessary to have an additional bonus/penalty system based on the rate of infections that occur *after* 7 days.
- Poor quality of service that results in a patient developing preventable conditions that increase the provider's payment level for services to those patients. For example, if the provider is receiving a condition-adjusted payment for primary care which increases the payment amount for patients who are obese, then it may be necessary to have a bonus/penalty system based on the rate at which patients become obese while under the provider's care.

The further that payment reforms move toward a total episode-of-care or global payment structure, the less need there will be for quality adjustments in the first category, because more and more of the corrective services will be covered by the payment itself, thereby internalizing the incentive to maintain quality. The need for quality adjustments in the second category will depend on the length of warranties and the length of provider contracts. For example, if a provider has a five-year payment contract with a payer, they will be accountable for the costs of addressing quality problems that manifest themselves within the five-year term of the contract (e.g., a failure to perform preventive cancer screening where a missed malignancy could significantly worsen within five years), but not for problems that occur more than five years in the future.[39]

Because of this, it seems likely that quality measurement focused on *preventive care* – where problems will often not manifest themselves until many years in the future – will take on enhanced importance for both explicit payment incentives and public reporting under more global payment structures. Fortunately, this is the area where most community-based public reporting programs now focus their efforts.[40]

This does not mean that other types of measures will not be needed; indeed, they will become even more important. However, the primary customers of the measures will no longer be payers, but the healthcare providers themselves, who will need effective ways of measuring and monitoring their performance since *they* will now be financially responsible for the problems poor performance causes, rather than payers. Moreover, rather than having outside entities imposing requirements for public reporting of these measures on the providers, the providers with the best performance will have a strong incentive to advertise their good performance to the public in order to attract more patients, and they should, in principle, welcome the existence of a community reporting program which can certify their good performance to the public.

D. Special Challenges for Small Providers

Pricing, limiting risk, and ensuring quality are more challenging for providers who care for a small number of patients, such as small physician practices and small hospitals. For example, if a small physician practice has taken accountability for the rate of hospitalizations for chronic disease patients, or if a small hospital has offered a warranty for infection rates, it is more likely that the rates of hospitalizations and infections for that practice and hospital will vary significantly from year to year solely due to random variations in the characteristics of patients and unique events than would be the case for larger physician practices and hospitals. Condition-adjustment systems can compensate for systematic variations, but they cannot compensate for the large impact caused when one or two patients turn out to be unusually expensive for reasons that could not have been anticipated in advance. Outlier payments or reinsurance can compensate for unusually expensive patients, but even the outlier limit or reinsurance threshold represents a higher proportion of total revenues for a smaller provider than for a large provider.

A similar problem arises with quality measurement. It is frequently impossible to generate statistically meaningful and reliable measures of the quality of care delivered to a small number of patients, since a single patient can dramatically change the success or failure rate in meeting a particular quality goal.[41] For example, suppose that patients get infections 1 out of 1,000 times after a particular procedure is performed. If a provider who performs the procedure on 1,000 patients has one patient who gets an infection, its measured infection rate would be 1 out of 1,000, which is the expected level. However, if a provider who performs the procedure on 10 patients has a patient who gets an infection, it would be impossible to tell whether the provider's "true" infection rate was 1 out of 1,000 or 1 out of 10, with the latter being 100 times higher than expected.

PAYMENT REFORMS NEED TO BE CUSTOMIZED TO HELP SMALL PROVIDERS PARTICIPATE, PARTICULARLY DURING THE TRANSITIONAL PHASES

In short, when a provider is small, it is difficult for the provider itself to accurately determine whether it is improving cost and quality outcomes and even harder for any payer to do so, since the payer will only be concerned about its own subset of the provider's patients. Moreover, small providers may not have either the information systems or staff with the time and expertise to analyze data in a meaningful way.

The solution is not to limit the payment reforms to large physician groups and hospitals, because this would preclude the majority of physicians and hospitals in the country from participating (e.g., over 80% of the physician practices in the country have only 1 or 2 physicians) or result in consolidations of providers that then discourage price-based competition. Instead, payment reforms need to be customized to help small providers participate, particularly during the transitional phases. Several possible techniques for doing this are:

- **Focus payment reforms on larger patient populations and/or on cost/quality targets that occur frequently.** The challenges in measuring costs and quality described above are a function of both the number of patients involved and the frequency with which the measured processes or outcomes occur. It is difficult to accurately measure a provider's performance on an adverse event that occurs rarely if the patient population is small, but it is less difficult to do measurement for processes or outcomes that occur more frequently and for types of patients that the provider sees more of.
- **Use different risk corridors or quality categories for different sizes of providers.** Rather than establishing a single risk or quality threshold that is independent of the number of patients cared for, a more flexible standard could be established that varies based on the number of patients that a provider cares for. For example, a 2% risk corridor might be established for a smaller provider (i.e., the provider would only be responsible for costs up to 102% of the payment amount), but a 4% risk corridor could be used for larger providers, since there would be a much higher probability that a 2% higher cost could occur by chance for the smaller provider than for the larger provider. Conversely, bonus payments for the smaller provider might be limited to situations where costs were at least 4% below expected levels, whereas the larger provider might be rewarded when costs were only 2% below expected levels, because there would be less likelihood that a 2% cost reduction for a large provider was due purely to chance. In other words, a smaller provider would need to achieve a bigger impact on outcomes (higher quality, lower cost, or both) to achieve rewards than would a larger provider, but the smaller provider would also have greater protection against uncontrollable increases in costs. This would provide an *incentive* to the smaller provider to join with other providers to form a larger organization such as an Independent Practice Association (thereby allowing it to receive "credit" for smaller outcome improvements) without *requiring* it to do so. At the same time, it would allow a high-performing small provider to remain small and still be rewarded for its high performance.
- **Use measures and standards applicable to individual patients, rather than those applicable to groups of patients, or define measures in terms of broader categories of patients.** For example, if bonuses or penalties are defined in terms of individual patients (e.g., a physician practice is only paid for a visit with a diabetic patient if a hemoglobin A1c test is performed) rather than a group of patients (e.g., a physician practice is paid a bonus if its rate of HbA1c testing is above average), then the size of the provider's patient population is irrelevant. If a composite measure is used that is applicable to all patients (e.g., a measure of whether "all preventive measures are up to date") instead of individual measures only applicable to specific types of patients (e.g., a measure of whether "mammograms are given to women in a particular age group"), then the provider's performance can be measured more accurately because it is calculated over all of its patients.
- **Measure performance across all of a provider's patients, not just those associated with an individual payer.** This cannot be done effectively by any payer alone, particularly in regions where there are many different payers, but it is being done in many communities by Regional Health Improvement Collaboratives which pool quality data from multiple payers to measure the performance of small providers more accurately and comprehensively.[42] Although payers naturally will want to ensure that their own patients are not getting care from the provider that is worse than average among the provider's patients, it is unlikely that the provider will even know at the point of care which payer is responsible for payment, so the chances of systematic differences in care quality are low. Moreover, a growing number of Regional Health Improvement Collaboratives are measuring disparities in the quality of care across different patient populations.

V. Developing a Transition Strategy

A. Choosing a Starting Point

With so many options for designing payment reforms, where should a community start? In choosing initial incremental steps in payment reform, the overarching goal should be to design steps that can be successful, quickly, from the perspectives of all major stakeholders:

- **For Providers:** The payment change should require manageable changes in care processes and affordable investments by providers, without putting them at significant risk of large financial losses;
- **For Purchasers and Payers:** The payment change and associated changes in healthcare delivery should produce financial savings to purchasers and payers in a relatively short time period and require modest changes in claims processing and other information systems. Ideally, the time period for receiving some financial return should be less than one year, since many purchasers must manage annual healthcare spending budgets, and health plan premiums are often adjusted annually. This is particularly important for state Medicaid programs, which need to achieve savings during the same fiscal year in which any enhanced payments are made.
- **For Consumers/Patients:** The changes in healthcare delivery made in response to the payment reform should improve the quality or affordability of healthcare services from consumers/patients' perspective, such as by reducing undesirable outcomes, improving access to desirable services, etc.

From a provider's perspective, it makes sense to start with patients and conditions for which most of the patient's needs can be met by services that the provider delivers itself, since it is easier for a provider to take accountability for its own services than for those delivered by other providers. For example, patients with mild and moderate stages of chronic disease are much more likely to be manageable primarily through the services that a primary care practice offers, whereas patients with more advanced stages of the disease are more likely to need a consultation with a specialist. The primary care practice could begin its transition to payment accountability by taking full risk for its own services and partial risk for specialist services and hospital stays for the mild/moderate stage chronic disease patients. Then, as it develops closer working relationships with specialists and hospitals, it could both expand the types of patients it takes accountability for and expand the level of risk it takes for services delivered by other providers until it reaches full accountability for all services and all patients.

This means that some providers will be able to accept more accountability more quickly than others. A multi-specialty group practice or IPA will be able to accept more accountability for more services and more types of patients because it delivers specialty services itself which in turn gives it more direct control over hospitalizations. An integrated healthcare system which operates hospitals and employs both primary care physicians and other specialists should be able to accept full or almost full accountability for all services and all patients. However, since these large systems deliver only a small proportion of healthcare in the U.S., if new payment systems are only designed for them, there will be little impact on the nation's overall costs and quality.

From the perspective of purchasers and payers, the following are four basic criteria for choosing an initial step that will help to maximize the likelihood of significant, short-term success:

- **Focus on conditions which affect a large number of patients.** Even small improvements in efficiency or effectiveness can have a significant aggregate impact when applied to conditions affecting large numbers of patients. Moreover, even small providers are likely to be able to participate in payment and care delivery changes affecting common conditions. For example, a large proportion of most providers' patients have chronic diseases, so payment reforms focused on chronic diseases will likely provide an opportunity for broad participation by providers and the potential for large amounts of savings. For commercial and Medicaid populations, pregnancy and newborn care represent a relatively large share of patients and costs.

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- **Focus on services where there is evidence of overutilization or inefficiency involving relatively large amounts of spending.** Even small reductions in overutilization or improvements in efficiency can generate significant savings when applied to expensive services. For example, a large proportion of spending on patients with chronic disease is used for potentially preventable hospitalizations, and a large proportion of spending on maternity care goes to avoidable Cesarean sections, avoidable elective pre-term inductions, preventable low birthweight babies, etc. There is evidence of significant overutilization of many kinds of surgery (particularly cardiac surgery and orthopedic surgery, which involve many patients), high-technology diagnostic imaging, etc.

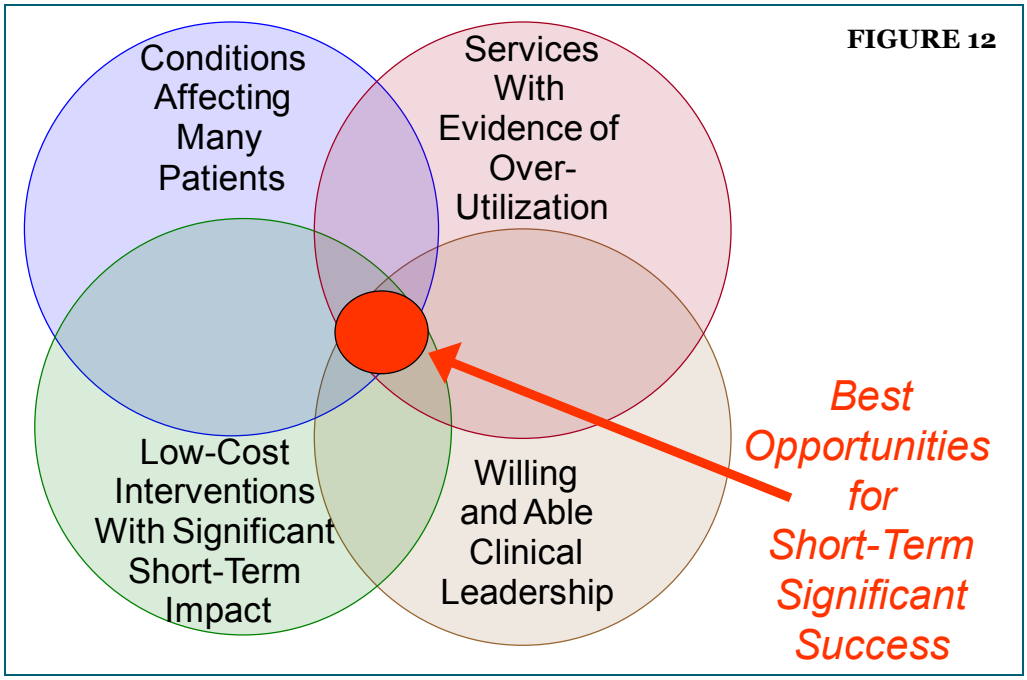


FIGURE 12

- **Focus on changes in care that have been proven to reduce overutilization or inefficiency, that are relatively simple or low-cost to implement, that can achieve significant results within a relatively short time period, ideally a year, and that are viewed favorably by patients.** For example, relatively low-cost programs that provide better patient self-management support and better discharge transitions have been demonstrated to quickly reduce preventable hospitalizations and rehospitalizations. Clinical guidelines defining the appropriate conditions for use of Cesarean sections, pre-term elective inductions, high-technology diagnostic imaging, etc. have been demonstrated to reduce overutilization of these services and can reduce costs and improve outcomes from the patient's perspective. Shared decision-making between clinicians and patients has been demonstrated to reduce rates of surgery and other expensive interventions in ways that patients view as desirable.[43]

- **Focus on services, conditions, and care changes where there is strong clinical leadership in the community.** Even if there is evidence of overutilization or inefficiency and evidence from other communities that this can be reduced, the changes must be made by the physicians, nurses, and other healthcare practitioners who actually deliver the care. Faster progress and greater success is likely to occur if they are enthusiastic participants than if they are unwilling or even resistant to making the changes.

As suggested in Figure 12, the best opportunities will exist where all four of these criteria are met, but even opportunities that meet two or three of the criteria will have good chances of success.

B. Keeping the End in Sight

When developing a transitional payment strategy, it is important to try and define not only the initial incremental steps, but also the desired end point (i.e., the payment system that is ultimately to be used) and as many of the intermediate steps as possible. There are two important reasons for this:

- From a provider's perspective, this helps strengthen the case for making significant investments in infrastructure, personnel, and processes of care if these investments would not pay off under the initial, incremental reforms but would be worthwhile under later transitional stages. For example, if there were a desire to have physician practices accept risk for hospitalizations of their patients, an initial step might be to have them take responsibility for a small portion of their patients' hospital costs; although the small share would limit their downside risk, it would also provide relatively little incentive for them to make significant investments in systems that would reduce hospitalizations. However, if they knew that the level of risk-sharing would increase in future transitional steps (e.g., through wider risk corridors, as described in Section IV-B-2), they would be more likely to make those investments to better position themselves for that future arrangement.

- From a payer's perspective, this could mitigate any concerns about providers "gaming" more limited payment reforms. For example, if there were a desire to have hospitals accept greater accountability for the full costs of episodes of care, an initial step might be to have them accept a single payment that includes the costs of readmissions, but not post-acute care costs. This could create an incentive for a hospital to significantly increase the use of home health care for discharged patients, but if it knew that a future transitional step would also bundle home health care into the single payment, then the hospital would have an incentive to ensure that home health care was not being overutilized when lower-cost ways to reduce readmissions were available.

The lack of a clear transition strategy is likely one of the reasons that many pay-for-performance systems have had limited impact on the delivery of care. The amount of money involved in most such systems represents only a very small percentage of revenues for most providers, and there is no indication as to whether or how much the P4P incentives will increase in the future, so providers may not see a significant return for making major investments in quality improvement. On the other hand, if it were clear that the share of payment devoted to quality incentives would be increased in the future, more providers would see the initial steps as an opportunity to restructure their processes in order to take maximum advantage of the larger incentives when they are implemented.

Similarly, a problem with payment reform "demonstrations," i.e., time-limited changes in payment systems wherein payment reverts back to the current system at the end of the demonstration, is that there may be little incentive for a provider to make significant investments in infrastructure, personnel, or new processes of care to enable success under the new payment model if it has no assurance that the revised payment incentives will continue after the end of the demonstration.[44] A better approach is what the Medicare program refers to as "pilots," which can be automatically continued if the initial experience with the payment reform is positive, but even pilot projects can create too much uncertainty for providers about how aggressively to pursue major changes in the way they deliver care.

This does not mean that either a precise timetable for the transition or the exact structure of all intermediate steps has to be locked in. For example, it may not be possible up front to determine just how quickly providers will develop the ability to accept greater accountability for the costs and quality of care for various types of patients and conditions. If the transformation of the delivery system occurs more rapidly than expected, then the transition timetable could be shortened and/or some incremental steps could be skipped. Conversely, if the transformation happens more slowly, the timetable could be extended and additional intermediate steps added. The key is for everyone to have a good sense of "what's coming next" and the timeframe in which transformation needs to occur.

C. Examples of Multi-Step Transitions

How a Hospital Could Transition to Accountable Payment

Suppose that a hospital and the physicians who practice there wanted to move to being paid using full episode-of-care payment, but had no experience with such systems. A multi-step transitional payment approach might be structured as follows:

- **Step 1:** The hospital decides to start by focusing on one of its highest volume groups of surgery patients, such as orthopedic surgery, where it believes there is an opportunity to reduce costs and improve the quality of care. It reaches an agreement with its orthopedic surgeons to accept a single bundled payment for each major type of orthopedic surgery (e.g., hip replacements) that will cover both the hospital services and the surgeon's fee. The combined payment is set at a level slightly below the sum of the previous DRG payment to the hospital and the case rate to the surgeon, based on an expectation by the hospital and the surgeons that by working together, they can deliver more efficient care with equal or better quality (e.g., by reducing the number of different brands of orthopedic implants used by multiple surgeons, by redesigning the flow through the operating rooms to make them more efficient, etc.). A Physician-Hospital Organization is created as a joint venture between the hospital and the orthopedic surgeons to receive the bundled payments and divide them between the hospital and physicians in ways that reward each for successful efforts to reduce costs. Payments for all other types of patients in the hospital would continue to be made on the same basis as in the past.
- **Step 2:** The hospital and surgeons expand the single payment to include the fees paid to all other consulting physicians on the orthopedic surgery cases. The combined payment is set at a level that is slightly below the average aggregate level of payments to the hospital and all physicians over the past year. The hospital, surgeons, and other physicians work together to define and implement guidelines for how all physicians should participate in these cases.

Other physicians, such as anesthesiologists, now have an incentive to help identify additional ways to reduce the cost and improve the quality of care.

- **Step 3:** The hospital and physicians expand the single payment to include the costs of any complications that occur during the hospital stay. For example, if the patient gets an infection during surgery or during recovery and develops additional preventable conditions, the hospital and physicians would agree not to charge extra for treating those conditions. In return for providing this "limited warranty," the payment amount would be higher than under Step 2, but it would be lower than the average amount the payer paid for the care of similar patients in the past (including the additional payments that were made for treating preventable complications). The hospital and physicians now will be financially rewarded if they reduce infections, rather than being penalized.
- **Step 4:** The hospital and other types of surgeons define similar warrantied, bundled payments for other types of surgery, based on the successful experience of the orthopedic surgeons.
- **Step 5:** The hospital and physicians other than surgeons work together to define a bundled, warrantied payment for certain types of *medical* admissions. For these types of cases, *all* physicians have been paid in the past on a fee basis, but a similar two-step process might be used – first creating a combined payment just for the hospital and the physicians in the specialty that typically manages such admissions, and then adding in payments for consulting physicians.
- **Step 6:** The hospital reaches agreements with a number of post-acute care providers, such as home health care agencies and inpatient rehabilitation facilities, to create a bundled payment for one or more types of admissions that includes both the costs of hospitalizations and post-acute care services. The amount of the combined payment is set at a level slightly below the average amount that would otherwise have been paid based on the historical rate and cost of post-acute care for the types of admissions for which the payment is being changed.
- **Step 7:** The hospital expands the inpatient bundled payments for one or more types of admissions to include not only the costs of the initial hospital stay and post-acute care, but also any hospital readmissions that are related to the initial stay. Initially, only readmissions that occur within 15 days of discharge might be included, but the payment could then be expanded to include readmissions that occur within 30, 60, and ultimately 90 days after discharge. The amount of the payment is set slightly below the total amount that would otherwise have been paid for both admissions and readmissions based on the historical rate and cost of such readmissions, since the hospital and physicians believe that they can reduce the number of readmissions through better care in the hospital and during the discharge process.

The hospital and the physicians who work there are now accepting bundled, warrantied, full-episode payments for the conditions representing the majority of their revenues, and they are able to deliver significant savings to payers and better outcomes for patients with healthier financial statements for all involved.

How a Primary Care Practice Could Transition to Accountable Payment

Suppose that a primary care practice that is currently paid entirely through fee-for-service payments wanted to accept greater accountability for the total cost of care for its patients in return for having greater flexibility and control over the services that its patients receive. Ultimately, it hopes to be able to accept some form of global payment arrangement for managing its patients, but it does not have the skills or experience to do that immediately. A series of transitional payment reforms could be structured to enable the practice to accept greater accountability in increments as it builds its capacity. The following is just one example of how a transitional payment reform might be structured:

- **Step 1:** The primary care practice decides it wants to start by focusing on a subset of its chronic disease patients (e.g., the patients with congestive heart failure or chronic obstructive pulmonary disease) and working to reduce the rate at which those patients are hospitalized (or readmitted) for preventable exacerbations of those conditions. Payers agree to add a new Care Management Payment component to their payments to the practice so the practice can hire a nurse care manager to provide patient education and self-management support to these patients, to install a patient registry, etc. A pay-for-performance component is also included based on the practice's success in reducing hospitalizations. If the practice is unsuccessful in reducing hospitalizations, the most it can lose is the cost of the nurse care manager and the registry software; if it is successful, it will receive not only sufficient new revenue to cover those costs, but also revenue enabling it to increase its profit margins and pay higher salaries to the physicians and staff of the practice.

- **Step 2:** The physician practice has success in reducing hospitalizations for the initial subset of chronic disease patients, and it expands the program defined in Step 1 to include additional types of chronic disease patients, e.g., those with asthma, diabetes, etc.
- **Step 3:** The physician practice recognizes that some of the most complex patients are still being hospitalized frequently, and it feels that greater involvement of specialists and coordination of care with them could help improve patient outcomes. The practice works out a cooperative arrangement with several specialty physician groups to jointly take accountability for the hospitalization rate of these complex patients, and the payers agree to pay the specialty groups for consultations with the primary care practice, but with rewards/penalties based on the success in reducing hospitalizations for these patients.
- **Step 4:** The primary care practice is sufficiently comfortable with its ability to manage the rate of hospitalizations for patients with certain chronic diseases that it agrees to accept a condition-specific comprehensive care payment for those patients. Instead of separate fees for office visits and other practice services, and in place of the new payment component added in Step 1, the payer(s) would make a single monthly payment to the physician practice for each of the patients with the relevant conditions. The amount of this payment would be adjusted based on the severity of each patient's conditions and other factors that could affect the cost of caring for them. Some patients with unusually complex combinations of conditions may be excluded from this payment and continue to be paid for under the current fee-for-service system, as would the practice's patients who do not have chronic diseases. The payment would be expected to cover the costs of all services those patients need related to their chronic disease, including specialists' fees and a portion of the costs of hospitalizations. The practice would not be expected to directly pay claims for hospitalizations or services delivered by specialists (unless it wished to); the payer would still process and pay claims, and it would treat the condition-specific comprehensive care payment amount as a budget against which the cost of all of the claims would be tabulated. The costs of the specialty consults defined in Step 3 would be covered by this payment.
- **Step 5:** The physician practice accepts similar condition-specific comprehensive care payments for patients with other chronic diseases, with partial responsibility for the costs of hospitalizations.
- **Step 6:** The physician practice is now managing condition-*specific* comprehensive care payments for so many different types of chronic diseases that it can comfortably agree to accept a condition-*adjusted* global payment for *all* of its chronic disease patients (or potentially all of its patients, regardless of whether they have chronic disease).

Different Transitions for Different Providers and Communities

These steps are merely illustrative. Some hospitals and physician practices may require more steps to make the transition, while others may require fewer steps or may be able to jump immediately to an intermediate step. Moreover, although the transitional approaches described above for physician practices and hospitals could be pursued independently of each other, there are also potential synergies between them. For example, once the local hospitals are able to offer a bundled, warrantied, full-episode payment for admissions for chronic disease exacerbations, physician practices will be more comfortable taking accountability for the total costs of care for their chronic disease patients, including hospitalizations, because they only have to worry about the rate at which admissions occur, and not about what those admissions will cost. Similarly, a hospital should be more willing to accept a single payment that covers the costs of hospital readmissions for chronic disease patients if the physician practices in the community are actively working to reduce preventable admissions for their patients who have chronic diseases and taking accountability for doing so.[45]

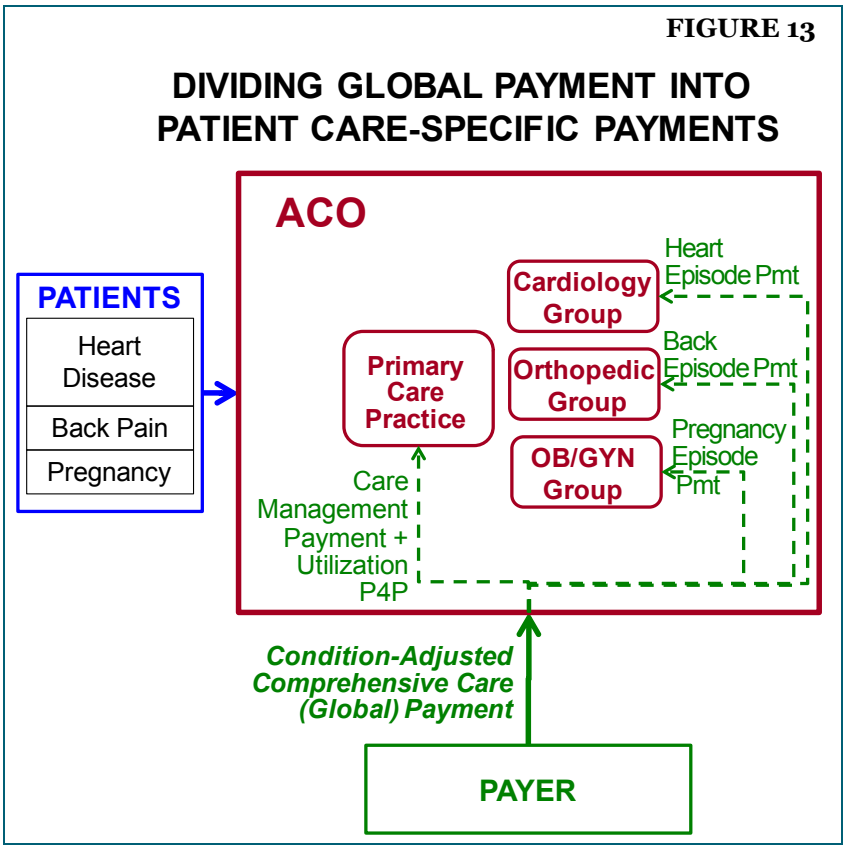
D. Creating Successful Accountable Care Organizations

An "Accountable Care Organization" or "ACO" is a provider or group of providers which takes accountability for controlling the total cost of care for a population of patients. Although many authors have discussed in great detail the technicalities of such issues as patient attribution, the statistical formulas for reliably declaring that savings have been achieved, and the legal issues associated with organizational consolidation, there has been almost no attention to what is a far more important question – how exactly will an ACO change the way healthcare is delivered in order to reduce costs and improve quality? While many providers are busy creating new organizational structures to manage the finances associated with payments to ACOs, new organizational structures do not directly translate into better care for patients or

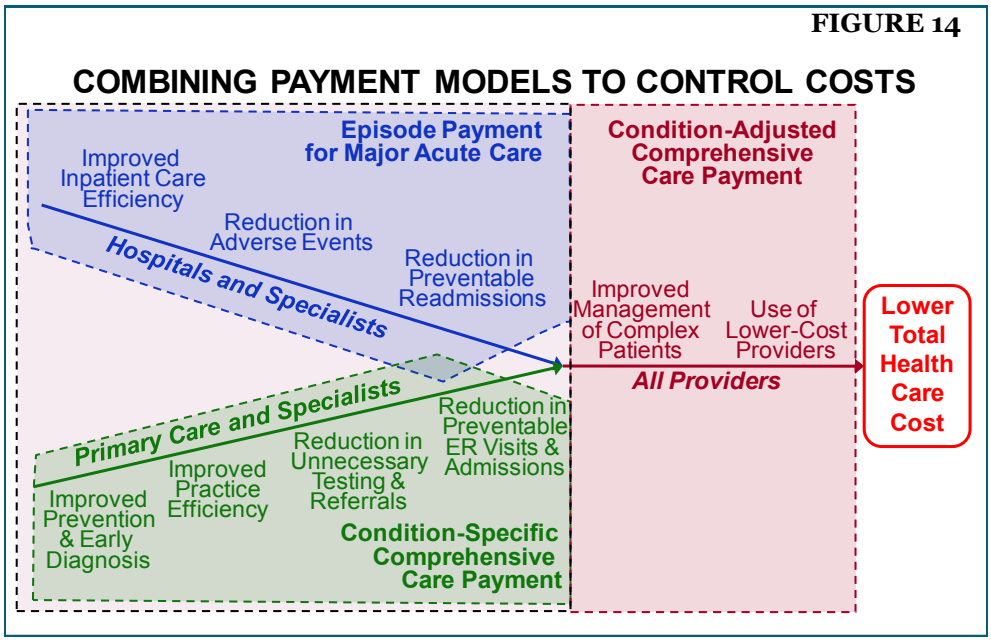
greater efficiencies in the delivery of that care.

The most important factors in the success of ACOs will likely be (1) their ability to identify specific opportunities for improving the way care is delivered to patients that can reduce costs and improve quality, and (2) their ability to provide the resources and supports that individual healthcare practitioners need to enable and encourage them to make those improvements. Even if the ACO is accepting a global payment for the total costs of care for a patient population, in order to successfully provide high-quality care at a cost less than or equal to the payment amount, it will need to break that payment budget down into sub-units and ask individual teams of healthcare practitioners to manage the care they deliver within those sub-units.

For example, as illustrated in Figure 13, in order to improve the total costs and quality of care for a group of patients with conditions such as heart disease, back pain, and pregnancy, the ACO will need to have cardiac care teams improving the cost and quality of care for patients' heart disease, orthopedic groups improving the way back pain is managed, maternity care teams improving the cost and quality of care for pregnant women, and teams of primary care physicians, specialists, nurses, and others improving the cost and quality of care for patients with chronic disease. An ACO cannot control *total* costs and quality if it cannot control both the cost and quality of individual episodes of care and the number of episodes of care for groups of patients, and it cannot control these things if the individual practitioners that are delivering the care are still being paid based on volume rather than value. So the ACO will need to make the equivalent of episode payments and care management payments to the individual physician groups and other providers involved in delivering the care.



As explained in more detail in *Creating Accountable Care Organizations*[46], many opportunities for reducing costs can be addressed primarily through the actions of primary care practices; others can be achieved primarily through the actions of hospitals and specialists; and some will require efforts by a broad range of providers in the community acting in concert. In order to maximize the impact on total costs, each of these providers will need to be paid in ways that support their efforts using the kinds of approaches described in Sections II and III, with the individual payment components adding up to the overall global payment.



VI. OBTAINING SUPPORT FROM PAYERS

A. The Myth of the One-Size-Fits-All Payment Reform

An implication of the preceding sections is that multiple new payment models need to be available in each community for providers with different capabilities, that different combinations of models will likely be needed in different communities, and that these payment models should evolve over a multi-year period as providers transition toward greater accountability.

Although it might seem much easier and cheaper to try and choose one "best" payment system and stick to it over a long period of time, doing so would serve as a major barrier to achieving the better value in healthcare that the nation desperately needs. Given the diversity of provider capabilities across the country, any one-size-fits-all payment change would mean that (1) those providers which could accept greater accountability than permitted by the payment change would be unable to deliver all of the improvements in value they could offer, and (2) those providers without sufficient skills to participate in the payment model that is chosen would be unable to make even the small improvements in value they could offer if given the opportunity to participate in a more incremental payment reform.

Although offering multiple new types of payment may sound very complex and expensive, it is difficult to imagine that the payment systems described in Sections II and III, even with multiple options to facilitate the transition, could be any more complex than current payment systems. For example:

- Medicare currently has not one, but four different methods of paying general acute care hospitals –one system for Critical Access Hospitals, a different system for Sole Community Hospitals, yet a different system for Medicare Dependent Hospitals, and finally the Inpatient Prospective Payment System (IPPS) for all other hospitals, and the IPPS system has further modifications for Rural Referral Centers, Disproportionate Share Hospitals, and teaching hospitals. Under the IPPS, Medicare pays hospitals separate prices for over 700 different MS-DRGs.
- Physicians are paid for over 8,000 different types of activities and procedures classified under the CPT code system, and Medicare determines fees for each of these separate codes based on three separate relative value units (RVUs) – work RVUs, practice expense RVUs, and the malpractice expense RVU – each of which is in turn modified by separate Geographic Practice Cost Indexes.
- Most providers are paid using a variety of different payment systems, some superficially similar but with many specific differences (e.g., different P4P standards from different payers), and others significantly different (e.g., many hospitals are paid using DRGs for some patients, per diem payments for others, and percent-of-charges for still others).

The transitional payment models described in Sections II and III could actually help to simplify many of the payment structures that are currently in place.

B. Aligning the Payment Systems of Multiple Payers

Most healthcare providers receive payment for their patients' care from multiple payers, including:

- The federal Medicare program;
- The state Medicaid program and other public programs;

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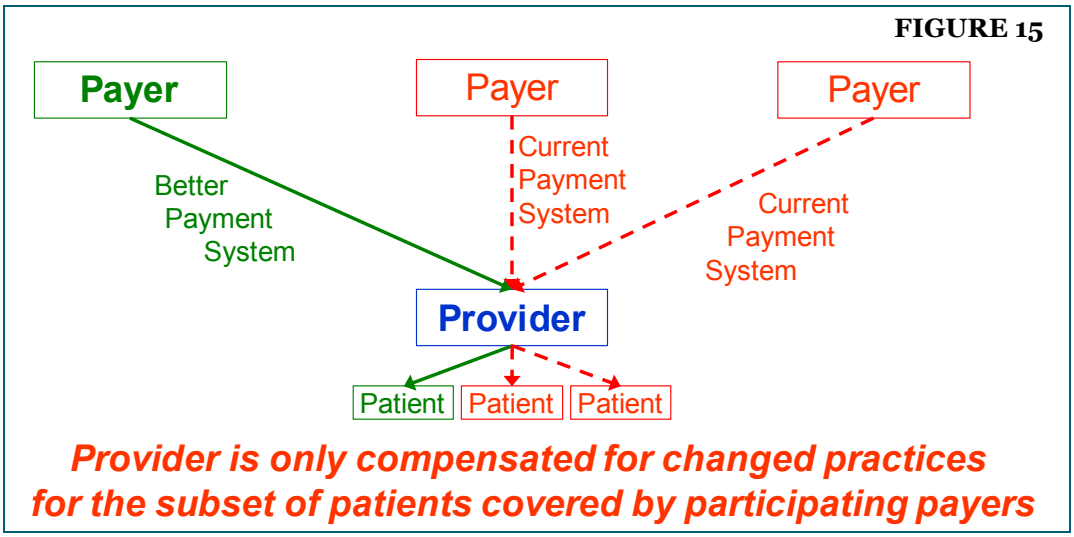
- National or multi-state commercial insurance companies (including Medicare Advantage plans);
- Local commercial insurance companies (including Medicare Advantage plans);
- Self-insured companies and organizations (including governments, for-profit businesses, and non-profit organizations), which typically use a national or local health plan to process and pay claims; and
- Self-pay patients.

Why Providers Need Alignment of Payers

Even if one payer is willing to implement desirable payment reforms, it is difficult and may even be inappropriate for a provider to change the way it delivers care for only that payer's patients. Consequently, if other payers do not also implement similar reforms, the provider faces an undesirable choice between:

- improving the way it delivers care for *all* of its patients, and being financially penalized for those patients still paid for under the payment systems that have *not* been changed;
- continuing to provide care for all patients the same way as in the past, and either refusing to participate in the new payment system or, if refusal is not an option, losing money for the patients paid for under the new system.



Why Payers Need Alignment of Payers

Payers may also be deterred from implementing a new payment system if they believe that other payers will not implement the same payment approach. If the payer contemplating the payment change does not have a large enough number of patients to ensure that providers will change the way they deliver care, then that payer would incur the costs of making the payment change with no corresponding savings in care delivery costs. Conversely, if that payer does have a large enough number of patients to convince a provider to change the way it delivers care, the provider will likely also generate savings for other payers without them having to incur the costs of making the payment change. In either case, the payer making the change is placed at a competitive disadvantage compared to other payers who do not make the change.

Overcoming the Barriers to Alignment

This means that it is in both payers' and providers' interest (as well as in the interest of patients) for all payers to adopt a new payment arrangement, since this would enable a healthcare provider to change its care processes for all of its patients without being financially penalized for any of them, while also avoiding creating a competitive advantage for any individual payer.

Despite this, achieving alignment of all payers in a market is very challenging, for at least two reasons:

- Concerns about antitrust law violations make it difficult for payers to discuss or reach agreement on a common approach to payment.
- Many payers pay for patients located in multiple geographic markets, and in some cases nationally, and they find it more efficient to use the same payment system in all of their markets, rather than having different payment systems

in each market that align with other payers in that market. This is true of Medicare itself, national and multi-state health insurance firms, and even large self-insured employers.

Although alignment of all payers would be ideal, many providers have indicated that having at least 50% of their patients covered under a better payment system would likely provide sufficient critical mass to enable them to implement different care processes.

It is unclear to what extent effective payer alignment should mean having payers adopt *identical* payment systems or merely that all payers need use to payment systems that provide *similar flexibility and incentives* to providers. The answer will likely depend on the extent of the administrative burden imposed on providers for complying with different payment systems. For example, many providers complain today about the enormous variation in pay-for-performance bonus programs among commercial health plans. Although at the most general level, one could say that two payers are aligned if they each have a P4P program that rewards high quality performance for a particular type of patient, different measures of what constitutes "high quality performance" in each payer's system mean the provider has to devote a higher level of administrative attention to being able to measure and report quality in multiple ways.

Some approaches that could be used to achieve a critical mass of multi-payer alignment for providers include:

- Use state government or a non-profit Regional Health Improvement Collaborative to facilitate agreement on a common payment methodology. Antitrust prohibitions focus primarily on payers agreeing on a common price for services, not necessarily on a common *method* of payment.[47] However, the risk of running afoul of antitrust laws will likely deter payers from discussing and agreeing on payment methodology changes without help from a neutral outside entity. One approach is for states to supervise the development of a common payment methodology, using the state action exemption under federal antitrust law. Another approach is for a neutral entity, such as a non-profit multi-stakeholder Regional Health Improvement Collaborative, to develop a common payment methodology and convince multiple payers to use it. For example, in a number of communities, non-profit Regional Health Improvement Collaboratives have developed agreement among multiple payers on a common payment methodology to support innovative care delivery programs or on a common set of quality measures that all of the payers will use in their pay-for-performance programs.[48]
- Reach initial agreement on a common approach to payment reforms among payers who exclusively or primarily pay for patients living in the local market. This could include:
  - the State Medicaid program.
  - locally-based self-insured employers. In many communities, the largest self-insured employers are health care systems, so these providers could actually take the lead in implementing the payment systems they want to see implemented more broadly.
  - local commercial health plans, including Medicare Advantage plans (Medicare Advantage plans are not limited to paying providers on the same basis as the traditional Medicare fee-for-service system).
- Restructure payment for types of patients and conditions for which there are fewer payers or who have payers that are more willing to change their payment systems. For example, there is no need to be concerned about participation by Medicare in order to change payments for maternity care; conversely, a major impact could likely be made on end-of-life care through changes in Medicare payment alone.
- Implement payment reforms with providers which accept payment from a more narrow range of payers (assuming those payers are willing to implement the payment reforms).
- Implement payment reforms initially with providers which have their own health plan. Providers which are integrated in this way will have greater flexibility in designing and evolving payment systems, since all revenues and costs for the patients in the health plan stay within the overall system.
- Define the most critical aspects of payment systems that need to be aligned, rather than trying to get all payers to implement the identical payment systems. The key issues for providers are that the incentives and disincentives in different payment systems be similar (e.g., the provider is not rewarded for more volume in one system and penalized for it in another) and that the administrative burden of complying with different systems not be high. It may be easier for different payers to implement similar incentives in different ways because of the unique structure of their information systems, the payment systems they use in other markets, etc.

C. How Medicare Can Participate

Given its size, it is very important that the Medicare program participate in new payment models for most types of providers. Fortunately, the federal Patient Protection and Affordable Care Act (PPACA)[49] has given the Centers for Medicare and Medicaid Services (CMS) the power to offer the full range of transitional payment reforms described in Sections II, III, and IV if it wishes to do so. The two principal sections of the law that provide this capability are:

1. Shared Savings Program/Accountable Care Organizations

Section 3022 of PPACA added Section 1899 to Title XVIII of the Social Security Act to support the creation of "Accountable Care Organizations (ACOs)." Although titled the "Shared Savings Program," subsection 1899(i) provides the Secretary of Health and Human Services with the power to establish "other payment models" for ACOs that the Secretary determines "will improve the quality and efficiency" of healthcare, as long as payments do not result in spending more "than would otherwise be expended … if the model were not implemented, as estimated by the Secretary."

Each of the transitional payment reform models described in Sections II and III above can be structured in a way that maintains or reduces spending for the services encompassed by the payment. For example, the Care Management Payment and Utilization-Based Performance Incentive for primary care described in Section III-A can be structured in a way that ensures that the increased spending for the Care Management Payments is offset by reduced spending on emergency room visits, hospitalizations, etc. Consequently, any of these transitional payment reforms could be implemented under Section 1899.

Although the "other payment models" can only be used by ACOs, the law defines ACOs quite broadly; physicians in group practices and Independent Practice Associations can qualify as well as hospitals employing physicians. Although it is generally perceived that only providers which deliver or control a full range of services would be able to qualify, the law says only that an ACO must "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." This could easily include organizations that are willing to transition over time to broad accountability but need more narrowly defined initial payment reforms to enable them to get started, similar to the sample transitional strategies outlined in Section V-C.

The Affordable Care Act gives Medicare the ability to participate in the full range of transitional payment reforms

2. Center for Medicare and Medicaid Innovation

The Shared Savings/ACO section of PPACA is not the only area where broad authority for payment reforms is granted; Section 3021 of the law added Section 1115A to Title XI of the Social Security Act, establishing the Center for Medicare and Medicaid Innovation (CMMI) within the Centers for Medicare and Medicaid Services. The purpose of CMMI is "to test innovative payment and service delivery models to reduce program expenditures … while preserving or enhancing the quality of care…" The law gives CMMI the power and/or duty to:

- test models focused on "a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures" (Section 1115A(b)(2)(A)), which allows targeting payment reforms on specific types of patients or health conditions where there are opportunities for savings, as suggested in Section V above;
- "limit testing of models to certain geographic areas" (Section 1115A(a)(5)), which allows different transitional payment reforms to be used in different areas as needed to match the capabilities of providers there; and
- focus on models "expected to reduce program costs…while preserving or enhancing the quality of care" (Section 1115A(b)(2)(A)), but not to require that the model is budget neutral initially (Section 1115(b)(3)(A)); this allows use of payment reforms which will achieve reductions in cost over a multi-year period.

This can allow Medicare to participate in unique payment models developed in individual communities to help their providers transition to more accountable care.

3. Making Medicare Claims Data Available

As described in Section IV-A, it is very difficult to set prices without access to data on current utilization patterns. It is also difficult to identify where opportunities for cost reduction exist or how to capitalize on them without access to such data. Healthcare providers need information on current utilization patterns and analyses of the likely impact of interventions in order to construct a feasible business case for the investment of resources in new care processes, and they will also need continuously updated data in order to monitor the success of these changes in care. Although many communities have multi-payer databases that can assist with this, these databases typically do not contain data on Medicare patients, which makes it impossible for providers to identify care improvement opportunities for Medicare beneficiaries or to design changes in care that will improve quality and reduce costs for the Medicare program.

It is critical that the Centers for Medicare and Medicaid Services make current Medicare claims data available quickly so that healthcare providers can begin planning successful strategies to take accountability for the costs and quality of care for their patients. An ideal approach is to use multi-stakeholder Regional Health Improvement Collaboratives as recipients of the data, protecting the confidentiality of the information while helping providers in their communities to analyze the data and plan appropriate changes in the way they deliver care.

It is critical that the Centers for Medicare and Medicaid Services make current Medicare claims data available quickly so that healthcare providers can begin planning successful strategies to take accountability for the costs and quality of care for their patients.

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2. In one survey, 20% of patients reported having received the same test that had been performed previously, much higher than in most other countries. The Commonwealth Fund Commission on a High Performance Health System. Why Not the Best? Results from a National Scorecard on U.S. Health System Performance. July 2008. Available at http://www.commonwealthfund.org.
3. For example, a number of projects have shown the value of having a nurse in primary care practices providing patient education and other care management services, but this is not a reimbursable service under Medicare or most health insurance plans.
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20. Instead of a Care Management Payment, new fees could be paid for specific services that are not currently compensated, such as phone calls or emails with patients, home visits or calls by a nurse care manager, etc. However, if the ultimate goal is to move to a payment structure that gives the physician more flexibility to determine the right mix of services for individual patients, then paying for currently-uncompensated services through a single per-patient payment would be preferable to creating a series of new fees that would each have to be individually priced and adjudicated for payment.

21. A list of medical home payment and technical assistance programs is available at the website of the Patient-Centered Primary Care Collaborative (http://www.pcpcc.net/pcpcc-pilot-projects). Also, the majority of state Medicaid programs pay at least some of their primary care practices a Primary Care Case Management payment, in addition to fees for service, to enable and encourage the primary care practice to improve the quality and reduce the cost of care to Medicaid beneficiaries.

22. For example, in the DIAMOND Initiative created by the Institute for Clinical Systems Improvement in Minnesota, psychiatrists are paid fees not just for seeing patients in the office, but also for consulting with primary care physicians and their care managers on how to better manage patients with depression. See www.ICSI.org.

23. The Massachusetts Coalition for Primary Care Reform is testing a comprehensive primary care payment model under which primary care practices receive a risk-adjusted comprehensive payment plus a risk-adjusted bonus for implementing medical home services and achieving desired outcomes. The concept is described more fully in Goroll AH, Berenson RA, Schoenbaum SC, Gardner LB. Fundamental reform of payment for adult primary care: comprehensive payment for comprehensive care. J Gen Intern Med. 2007 Mar;22(3):410-5.

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25. The condition-specific payment for diabetics might still be *condition/severity-adjusted* based on the comorbidities that the diabetic patients have (for example, the payment to the practice for its diabetic patients could be higher if their diabetes was more severe), or the conditions for which the payment is made could be defined in a way which excludes some particularly complex patients (e.g., a diabetic patient with three or more other major comorbidities could be excluded from the group of patients covered by the condition-specific payment, and services for that patient could continue to be paid using fee-for-service), or both. See Section IV-B for more discussion of this point.

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30. Miller, HD. From volume to value: Better ways to pay for health care. Health Aff (Millwood). 2009 Sept-Oct;28 (5):1418-28.

31. "Condition/severity-adjustment" is the same basic concept as "risk adjustment," but since the payment is being adjusted based on the patient's current status, not just on their risk of future needs, and since most risk-adjustment

systems are based primarily on the conditions the patient has, it seems clearer to refer to this as condition/severity-adjustment.

32. Risk-adjustment formulas are commonly evaluated based on what proportion of the variation in costs among patients they can explain/predict. However, this evaluation criterion is inappropriate, since a risk-adjustment formula cannot explain/predict something that has no logical underlying rationality – if different physicians treat patients differently purely based on the personal preferences of the physicians (or the patients), then no model based on clinical characteristics of patients will ever be able to explain or predict those differences. This is not a flaw with the models; in fact, the goal of having a condition/severity-adjusted payment system would be to pay physicians more for a patient who has more conditions that justify more services, but not more for a patient who is essentially identical to another patient but where the physician simply chooses to deliver unnecessary services.

33. Ultimately, condition/severity-adjustment systems will need to be modified to measure how patient conditions improve or worsen over time under the care of a particular provider; a provider could inadvertently be penalized financially for helping patients lose weight, stop smoking, etc. because the condition-adjustment would reduce payment when the patients improve, and the provider could be rewarded for their patients developing poorer health habits. See Miller HD. Making reform a reality: Ways to facilitate better healthcare payment and delivery systems and lower healthcare costs. Robert Wood Johnson Foundation, June 2010. Available at http://www.rwjf.org/files/research/64970.pdf.

34. CMS replaced the previous 538 Diagnosis Related Groups (DRGs) with 745 "Medicare-Severity DRGs" (MSDRGs).

35. It is worth noting that this problem exists even in the fee-for-service system, because fee levels are fixed for specific services. For example, if a physician's patients routinely require much more than the assumed amount of time for an office visit, the physician will lose money because he or she will be able to see fewer patients during the day than needed to cover their costs. Alternatively, compressing the visits to fit within the assumed time can result in failure to address all of the patient's needs appropriately, resulting in poorer quality of care and poorer outcomes.

36. For example, the Medicare DRG payment system for hospitals pays hospitals a fixed amount per case but includes a provision to pay an outlier payment to the hospital if a patient's costs significantly exceed the base payment amount.

37. For example, Medicare uses symmetric risk corridors in paying health plans for pharmaceutical costs incurred under the Medicare Part D prescription drug benefit. If a Part D plan incurs costs between 95% and 105% of a defined target amount, the plan is responsible for covering those costs with no additional payment from Medicare. However, if a plan incurs costs between 105% and 110% of the target, it is only responsible for 50% of those costs, and Medicare pays the remaining 50%; if costs exceed 110% of the target, the plan is responsible for only 20% of the costs, and Medicare pays an additional amount sufficient to cover the remaining 80%. If the plan incurs costs between 90% and 95% of the target, the plan refunds 50% of the savings in that range to Medicare, and if the plan's costs are below 90% of the target, it refunds 80% of the costs below 90% of the target to Medicare. The risk corridors were originally narrower in order to encourage private health plans to participate at a point where there was limited information about exactly how drug usage by Medicare beneficiaries might change in respond to the new program.

38. In capitation payment systems, this process of accepting risk and then contracting out portions of that risk on a similar basis is known as "subcapitation." Paying a hospital or specialty provider a specific amount for each patient who is referred to them, rather than a specific amount for all patients in a broader population group, is called "contact capitation," i.e., the payment is only made if the provider has contact with that patient, whereas in a traditional capitation system, a provider is paid the capitation payment even if a particular individual does not use any services from the practice.

39. Arguably, this also depends on the frequency with which patients change health plans, because the provider will not reap the savings from preventive care nor incur the penalties of failure to deliver such care to patients who move to a different health plan or provider. However, this would require the provider to predict which patients would switch and systematically deny care to those patients.

40. Links to measures of the quality of preventive services in various communities can be found on the website of the Network for Regional Healthcare Improvement (www.NRHI.org).

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48. Examples of multi-payer initiatives coordinated by Regional Health Improvement Collaboratives can be found at: http://www.nrhi.org/paymentdeliveryreform.html .

49. P.L. 111-148 and 111-152.

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Thomas H. Gallagher

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A 62-Year-Old Woman With Skin Cancer Who Experienced Wrong-Site Surgery

Review of Medical Error

Thomas H. Gallagher, MD, Discussant

After a life-threatening complication of an injection for neck pain several years ago, Ms W experienced a wrong-site surgery to remove a squamous cell lesion from her nose, followed by pain, distress, and shaken trust in clinicians. Her experience highlights the challenges of communicating with patients after errors. Harmful medical errors occur relatively frequently. Gaps exist between patients' expectations for disclosure and apology and physicians' ability to deliver disclosures well. This discrepancy reflects clinicians' fear of litigation, concern that disclosure might harm patients, and lack of confidence in disclosure skills. Many institutions are developing disclosure programs, and some are reporting success in coupling disclosures with early offers of compensation to patients. However, much has yet to be learned about effective disclosure strategies. Important future developments include increased emphasis on institutions' responsibility for disclosure, involving trainees and other team members in disclosure, and strengthening the relationship between disclosure and quality improvement.

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DR DELBANCO: Ms W is a 62-year-old woman who experienced wrong-site surgery when a lesion was removed from her face.

Several months ago, a pink, scaly plaque on her face was biopsied and diagnosed as a 0.5-cm^2 squamous cell carcinoma. Three months later, Ms W entered an operating room in a Boston, Massachusetts, hospital for surgery to remove the skin cancer.

The morning after her surgery, Ms W removed her bandages and discovered that the surgery had been performed on an area to the right of the lesion. Ms W feels that the surgery team marked an area of skin incorrectly before the surgery was performed and believes she would have identified the mistake if she had been given a mirror in the operating room to check where the lesion was marked.

After the initial surgery, Ms W began to experience shooting pain that spread from her nose to the left side of her forehead. The pain would surface 5 to 6 times per day, and she gained some relief by rubbing the area. She tried gabapentin but did not find it helpful. In addition, Ms W experienced significant swelling and bruising around her eyes and felt unable to work for a period of several weeks.

Several weeks later, Ms W underwent a second procedure to remove the correct lesion.

This was the second time Ms W experienced an untoward event following an elective procedure. Ten years earlier, Ms W had a pneumothorax after a trigger point injection into the trapezius muscle. Initially unrecognized by her surgeon, this led to a 2-week hospital stay, eventually requiring thoracic surgery. Ms W contacted an attorney at the time, and she was compensated by the hospital for the event. No formal legal proceedings were required.

Ms W is generally healthy. She drinks socially, exercises regularly, and does not smoke. She has private health insurance. With respect to medical history, Ms W reports having viral meningitis followed by what was termed postmeningitic fibromyalgia and tinnitus. She has had a hysterectomy and breast biopsies for benign disease and is thought by a neurologist to have cervical radiculopathy, with tingling in both forearms and hands and, occasionally, in her feet.

On physical examination, she looks well and has tanned skin from sun exposure. Physical findings are otherwise unremarkable. The surgical scars on her face are not readily visible.

Laboratory findings are unremarkable. Medications include an estradiol patch, alprazolam as needed for anxiety, multivitamins, calcium supplements, and daily aspirin.

CME available online at www.jamaarchivescme.com and questions on p 697.

This conference took place at the Surgery Grand Rounds at Beth Israel Deaconess Medical Center, Boston, Massachusetts, on November 5, 2008.
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Ms W is seeking compensation for pain, suffering, and time away from work.

MS W: HER VIEW

The night before my surgery, I dreamt that the surgeon was a sumo wrestler and that she was throwing knives at my nose. In fact, I told her that when she came. I recall saying, "I am obviously very nervous about having this surgery." I really didn't think I was, but my dream told me that I was. My doctor and I laughed about that.

After the surgery, I took the bandages off and looked in the mirror. At first, I couldn't believe it. I saw that they had operated on the wrong spot and I just . . . I started to scream. Because this was the second time that I experienced a medical error, the first emotion I felt was anger. I was furious! Incredulous and furious . . .

The apology was very clear. The doctor said, "I'm very sorry that this happened. This is my worst nightmare." When things went wrong the first time as a result of the injection, it took a while before people were able to acknowledge what had happened and the mistake that had been made. This time it was an immediate recognition and apology, and that was reassuring to me.

I had a meeting set up with the coordinator of the unit, and she asked me to go through what had happened: what I remembered of it, what I had experienced, and what it was like for me. She explained that they had changed the protocols already because I had told them that I was never given a mirror to see where the spot had been marked. If I had been, I certainly would have known right away that it was the wrong spot. I knew there was supposed to be a "time out" where there is some coordination between the staff. They are supposed to make sure that everything is all set before they actually go in and make an incision. I only remembered after the fact that that never actually happened.

I also knew that the hospital was making a great effort to be transparent about these things. There had been a lot of public acknowledgment that the hospital wanted to make it safer for patients. So having met with the head of risk management and quality assurance, I then made an appointment to meet with the director of the hospital. He gave me a meeting time, and we had a very good discussion. From each of these people, I received a very clear apology. They also all asked what they could do for me, which was another thing that was really very helpful.

I did know that I wanted some kind of compensation for this. I was unclear how it should be done or what I wanted, but I did know that it was something that I felt I wanted. I had lost time from work, and the experience was traumatic for me. I discussed this option with the head of the hospital, and he said that this was something they would absolutely consider.

One of the major regrets that I have had since this happened is that I never had an opportunity to talk with the fellow who marked the spot—who mismarked the spot. That person never appeared again. When I asked if I could have a chance to speak with the fellow, I was told that the person had already left the hospital and was not around any longer. I thought that was a real missed opportunity, both for the fellow and for me.

AT THE CROSSROADS: QUESTIONS FOR DR GALLAGHER

What is a medical error? How does it differ from an adverse event? How common are medical errors? What proportion of medical errors cause harm? What are patient expectations for communication following medical errors? Are they being met? What barriers inhibit disclosure of errors? How can they be overcome? How do disclosure and litigation relate? What role does communication play in responding to medical errors? What does the future hold with respect to open disclosure? What do you suggest to Ms W's physicians and the hospital? What would you suggest to Ms W?

DR GALLAGHER: Few events in health care are as upsetting for all involved as when a patient is harmed by health care, especially when the harm is due to a medical error.[1] The moment Ms W realized that her surgery was on the wrong site—representing the second major unexpected complication in her health care—she felt overwhelming incredulity, anger, and fractured trust. Even during the procedure she sensed that something was amiss: "*There just seemed to be a lot of pressure on people to get it over with, get it done. And I think I was picking up on that, but again I was trusting what they were doing. And I didn't think that I needed to do anything other than just be a good patient and lie there and let them take care of me.*"

Widespread consensus exists that patients like Ms W should receive prompt, full disclosure of the error and a sincere apology, a marked departure from the profession's historical "deny and defend" response.[2-9] Yet the development of effective disclosure is at an early stage.[10-12] Clinicians' commitment to disclosure is strong, but they struggle to turn this principle into practice.[13] According to published surveys in the United States, most hospital policies endorse disclosure,[14-16] but few clinicians have had disclosure training.[17] Even fewer institutions track whether disclosures have occurred or evaluate their quality. Sparse prospective data exist regarding effective disclosure strategies or how disclosure affects important outcomes such as patient trust and satisfaction or malpractice claims.[18,19]

Ms W's experiences highlight key crossroads for the participants in this error and the medical profession at large. Ms W must decide the best path to heal from her physical and emotional trauma and resolve whether she can trust not only the clinicians responsible for this error but also future health care professionals with whom she may interact. Her clinicians must choose both what to say to Ms W and whether institutional resources might facilitate disclosure. All clinicians must decide whether and how to improve their disclosure skills. Health care institutions face difficult choices regarding creating effective disclosure programs. Finally, the medical profession needs to determine how to establish accountability that will ensure that effective disclosure becomes the norm rather than the exception.

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What Is a Medical Error? How Does It Differ From an Adverse Event?

Ms W's wrong-site surgery clearly constitutes a medical error. However, a concise, comprehensible definition of medical error has proven elusive.[20] The most common definition is from the Institute of Medicine: "Failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim."[21] This definition emphasizes 2 important principles: (1) a bad outcome does not mean a medical error has happened and (2) medical errors are unintentional and generally preventable.[22,23]

It is important to distinguish between medical error and the related concept of an adverse event. An adverse event is "harm that is the result of the process of healthcare rather than the patient's underlying disease."[21] Thus, while *medical error* focuses on the process of care, *adverse event* addresses the outcome. The overlap between medical error and adverse event is small: most medical errors are not associated with harm, and most adverse events are not due to medical errors. However, Ms W experienced both: a medical error that caused an adverse event.

How Common Are Medical Errors? What Proportion of Medical Errors Cause Harm?

Medical errors are relatively common. A 2005 survey of 1527 randomly selected US patients who were active users of health care (affirmative response to ≥1 of following: self-rated health fair or poor; having serious or chronic illness, injury, or disability; hospitalized in the last 2 years; major surgery in the last 2 years) found that 34% reported having experienced a medical error in the past 2 years.[24] The epidemiology of medical error is best understood for medication errors. One study found 3.13 medication errors per 1000 orders in a large teaching hospital.[25] Medication error rates are higher in intensive care units and pediatric settings.[26,27] Adverse drug events are also common, with 6.5 occurrences per 100 nonobstetrical admissions.[28] Among these adverse drug events, 28% were preventable; ie, due to error. Studies of adverse events in general have found that they occur in approximately 4% to 14% of hospitalizations and that 50% to 70% are due to error.[21,29] Recent studies suggest that some types of adverse events, such as central-line infections, can be reduced to nearly zero,[30] leading patient safety expert Lucian Leape to assert that "it is now apparent that we can use perfection as a benchmark."[31]

Wrong-site surgeries, as experienced by Ms W, are rare. One study of 2 826 367 US operations found 25 wrong-site surgeries, a rate of 1 per 112 994 nonspine operations.[32] Contrary to the portrayal of these events in the media, only 1 of the wrong-site surgeries in this study was associated with permanent injury. Interestingly, the rate of wrong-site surgery appears unchanged despite the Joint Commission undertaking a major initiative in 2004 to reduce these errors.[33,34] This inability to reduce the rate of wrong-site surgery suggests that it may be exceedingly difficult to achieve the benchmark of "perfection," at least for some types of adverse events.

What Are Patient Expectations for Communication Following Medical Errors? Are They Being Met?

Ms W's expressed needs after this error are consistent with most patients' preferences for disclosure. They reflect 3 key elements: information; emotional support, including an apology; and follow-up.[3,35-37]

Following a medical error, patients are eager to understand what happened to them. Information sharing therefore is a cornerstone of disclosure. Patients expect harmful errors to be disclosed to them, even when the harm is minor. Ms W noted: "*I wanted to have an opportunity to go through what happened . . . then why did this happen? And the other piece of it for me was I don't want this to happen to anybody else, so what can be done to change the way it happened to me?*" Patients expect that physicians will share this information with them; patients want to be informed so that they can make better clinical decisions, and they want their physicians to demonstrate respect for them as individuals.[38-40]

Clinicians tend to focus on the information-sharing aspect of disclosure but often neglect patients' emotional distress.[41] Patients feel vulnerable in health care encounters, and harmful errors compound that vulnerability. Because of her prior experience, Ms W was especially nervous about facing her physicians again: "*After this side healed, then I had to have another biopsy and undergo another procedure.*" To remedy the mistake, could (or should) she trust the same physicians who caused her problem?

Apologizing to patients is an integral aspect of the disclosure process and constitutes a vital first step toward soothing the emotional distress and loss of dignity that accompanies medical errors. Ms W reported that the sincere apologies she received were instrumental in beginning to rebuild her trust. Although the apology after her first experience was somewhat delayed, she noted that "*the next day when he came in, he said 'I owe you an apology' . . . and so that was one of the best things. And it really established a sense of trust between me and that doctor who actually did have to operate on me.*" Ms W noted similar relief after the disclosure and apology following the recent error: "*This time it was an immediate recognition and apology, and that was reassuring to me.*"

The medical, legal, and health policy literature reflects different approaches to what constitutes an apology. At a minimum, it is an expression of sympathy, while some argue that an authentic apology includes admitting responsibility, showing remorse, offering an explanation, and making reparations.[42,43] Perhaps most important to the patient is whether the apology is sincere.[8,44] Simply saying "I am sorry that this happened" or "I am sorry to have to tell you about what's happened" does not, in most cases, constitute an effective apology. How patients determine and define an apology's sincerity is not well understood and likely depends on both verbal and nonverbal aspects of clinicians' communication and actions. For Ms W, the apology's sincerity appeared to hinge not on specific words exchanged but rather on whether the clinicians' and institution's subse-

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Table 1. Disclosure Barriers and Potential Solutions

Barriers	Potential Solutions
Clinician barriers[3,11,12,37,52,54]	
Fear that disclosure will prompt litigation	Learn about relationship between disclosure and litigation
Concern that disclosure will not benefit patient	Understand patients' preferences for disclosure, consequences of failed disclosure on patient-physician relationship
Lack of confidence in communication skills	Seek disclosure skills training Use disclosure coaches
Shame/embarrassment about error	Use institutional support resources
Institutional barriers[9,15,58]	
Concern that clinicians are not skilled in disclosure	Institute a disclosure support system, including training, coaching, and emotional support
Lack of awareness about deficiencies in current disclosure practices	Measure quality of actual disclosures
Perception that disclosure is a risk management rather than patient safety activity[47]	Engage patients in safety and quality activities, including event analysis

quent actions demonstrated to her that they were truly sorry about what happened.[45,46]

Ms W did not consider the disclosure finished after her initial discussion with the physician. Ms W sought multiple follow-up conversations with clinicians and administrators, suggesting that disclosure is a process rather than an event.[47] Follow-up conversations provide opportunities to share results of error analyses with patients and to respond to their questions. Continuing communication can also assuage patients' fears of abandonment after errors. Innovative disclosure programs, such as those at the University of Illinois Medical Center at Chicago, emphasize ongoing, proactive contact with patients after harmful errors, contacts that can extend for a year or more.[48] While the program's outcomes have not been studied in detail, preliminary results reported by the institution show that clinicians actively use the program and that 189 system improvements have been implemented in the last 2 years as a result of event reporting and analyses.[49]

A sizable gap exists between patients' expectations for disclosure and current practice. In surveys, only one-third of patients who report experiencing a harmful medical error say that the involved health care worker disclosed the error and apologized.[50,51] Moreover, disclosures that do take place may not meet patient expectations.[11,52-54] For example, physicians often fail to disclose why an error happened or how to prevent recurrences.[11,12,41]

The nature of the error seems to influence disclosure. Physicians' willingness to disclose is higher for obvious errors, as was Ms W's, compared with those unapparent to the patient.[11,55] Disclosure also varies by specialty, with surgeons disclosing less information than internists or pediatricians.[11,56] Recent studies of actual disclosures reveal considerable room for improvement. Evaluation of the Australian Open Disclosure program highlighted patient support for the overall open disclosure process but dissatisfaction with multiple aspects of their experience, such as the disclosure not being timely, that no change in practice followed the disclosure, the lack of an apology, and not being able to speak directly with involved staff.[57]

What Barriers Inhibit Disclosure of Errors? How Can They Be Overcome?

Multiple barriers, at both the individual clinician and institutional levels, can inhibit disclosure. TABLE 1 lists key disclosure barriers and potential strategies to overcome them.

Historically, the most frequently cited barrier to disclosure has been concern that disclosure could prompt litigation,[59] but this belief may have obscured the medical profession's awareness of more significant disclosure barriers. Many physicians worry that disclosure could do more harm than good to the patient and consider a decision not to disclose as "patient-centered care."[3] For other physicians, embarrassment and emotional distress after errors make it difficult to talk with the patient.[59] Still others lack the confidence to conduct these difficult conversations. Yet Ms W would not consider these reasons persuasive; why should her physicians not speak frankly with her?

As described below, overcoming such barriers requires a multifactorial approach, one that may hinge on institutional support for clinicians throughout the disclosure process.

How Do Disclosure and Litigation Relate?

The relationship between disclosure and litigation has generated considerable controversy.[60] For decades, disclosure decisions were dominated by concern that disclosure could trigger litigation, partly reflecting a handful of malpractice cases in which disclosure was taken in court as de facto admission of liability.[61] A fuller picture of the disclosure-litigation relationship emerged when research indicated that the absence of disclosure motivates many medical malpractice lawsuits.[62,63] Subsequent research goes further: disclosure may actually reduce litigation. Surveys using hypothetical cases suggest that full disclosure is associated with lower intention to sue, and mock jury studies suggest that jury verdicts may be lower when errors have been disclosed.[36,45,64,65] Moreover, individual institutions report that their policies of full disclosure lead to fewer lawsuits and lower legal expenses.[2,49,66]

Growing physician and institutional awareness of disclosure's potential to mitigate litigation have likely tempered exaggerated fear of disclosure's legal implications.[67] However, while disclosure may have an overall positive effect on litigation, it is far from a magic bullet. In some circumstances, disclosure will trigger litigation, especially if the disclosure conversation brings the error to the patient's attention.[68,69] Many states have adopted laws that protect disclosure and apology statements from being used as evidence of liability, but such laws do not mean that a disclosure or apology could not be the stimulus for patients to sue.[70-72] Evidence-based understanding of the disclosure-litigation relationship emphasizes

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that disclosure's primary goal is patient-centered care, not risk management.

What Role Does Compensation Play in Responding to Medical Errors?

As she reflected on what happened to her, Ms W believed compensation was important. Ms W valued the disclosure and apology but also wanted financial compensation: "*I did know I wanted some kind of compensation for this. I was unclear how . . . or what I wanted [but] . . . I had lost time from work, and the experience was traumatic for me.*" Even the best disclosure practice may not extinguish some patients' desire or need to have the financial consequences of an error addressed.

Traditionally, the primary way to receive financial compensation following a medical injury was to file a malpractice claim, a process that was slow, adversarial, and often resulted in injured patients remaining uncompensated.[68] Several health care institutions and malpractice insurers have developed "disclosure-and-offer" programs that combine full disclosure with early offers of financial compensation.[48] These programs have emerged at large academic health care institutions (University of Michigan, University of Illinois Medical Center at Chicago, Stanford University) and at malpractice insurers (COPIC Insurance, West Virginia Mutual, ProMutual Group). Preliminary evidence reported by the programs suggests a reduction in the number of claims, lawsuits, and overall legal expenses, as well as high levels of satisfaction among participating patients and physicians.[2,73,74] Compared with traditional claims mechanisms, these programs report also that the time to resolution of cases and defense costs are generally much lower for their disclosure-and-offer programs.[66] For example, Stanford University notes that the percentage of reported claims that have been closed in the same year they were opened increased to a 7-year high, and average claim costs for cases closed within the same year as reported decreased to a 7-year record low since it launched its disclosure-and-offer program (J. Driver, JD; Stanford University Medical Indemnity and Trust, written communication, June 2009).

Important questions about compensation and medical error remain, and the new approaches vary widely. Similar to national compensation strategies in New Zealand and Sweden,[75] COPIC's 3Rs program uses a no-fault approach to compensate certain unanticipated outcomes. Dealing with a small subset of unanticipated outcomes (excluding patient death, written demand for payment, written complaint, or gross negligence), it caps payments at $30 000 and prohibits attorney involvement. However, it does not ask patients to waive their right to file a subsequent lawsuit.[2,74] In contrast, Michigan's program applies to harm caused by inappropriate care. This effort permits negotiation with patients regardless of whether they have legal counsel representation and sets no payment limits but requests that patients waive their right to future litigation following settlement.[76] Finally, no national standards exist regarding how much compensation is reasonable for a given medical injury. Who should decide whether current disclosure-and-offer programs provide "fair compensation" to patients?

What Does the Future Hold With Respect to Open Disclosure?

The field of disclosure has seen rapid developments over the last decade. TABLE 2 summarizes some of the noteworthy developments and their implications.

Several developments hold potential for enhancing the disclosure process significantly. While the first disclosure standards made the physician the locus of control, new standards recognize that disclosure is essentially an institutional responsibility that begins at the board of trustees/chief executive officer level and extends throughout the organization.[7,47] This places institutions at an important crossroads: Will they invest the resources needed to create effective disclosure programs? As part of their disclosure program, will they commit to developing a culture in which open, empathic communication with patients following harmful medical errors is the norm?

The shift toward disclosure as an institutional responsibility does not mean that physicians will not play a central role in disclosures. New approaches to enhance physician-institutional collaboration around disclosure are needed, especially at hospitals with private medical staffs. Physicians face a related crossroads: Will they seek out resources to enhance their disclosure abilities, including basic disclosure training and just-in-time support from institutional disclosure experts?

While Ms W's disclosure conversation was just with her physician, in the future, additional members of the health care team may participate in disclosures. Institutions are increasingly recognizing that disclosure is a "team sport." Many errors occur in the context of team-based delivery of health care, yet it is rare that nonphysician members of the health care team are involved in planning or implementing disclosure discussions.[80] The disclosure process should seek input from all team members about what went wrong and how the event should be disclosed to the patient. But such interprofessional conversations can be complicated by the power differential that exists between physicians and nonphysicians. Having a few key team members accompany the physician to the disclosure can ensure that the patient's need for emotional support and information about the event is met; it also allows each team member to accept responsibility. Future research should seek to clarify when a team-based approach enhances or detracts from disclosure.

Performance improvement tools are also being applied to the disclosure process itself. In the future, Ms W may be asked to provide feedback on the quality of the disclosure conversations, much as patients currently are asked to report their health care experience through surveys and interviews. COPIC routinely measures patient and physician assessment of the quality of actual disclosures, finding that both parties provide valuable feedback about the disclosure process. It also found that instruments to assess disclosure do not have the ceiling effect common to many used to measure patients' assessment of their care (D. Boyle,

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MD, COPIC Insurance, written communication, June 2009). Routinely measuring the quality of actual disclosures would help target disclosure improvement efforts.

The health care profession faces the most significant crossroads: whether to develop a stronger culture of accountability around disclosure by all health care professionals. Will curricula and training ensure that clinicians enter practice proficient in disclosing harmful errors to patients? Will remediation be required when proficiency has not been achieved? Will state boards and specialty-certifying bodies ensure that disclosure is recognized and evaluated as a core competency? Will institutions make disclosure proficiency a condition of providing health care at their organization? Will insurers and purchasers insist that the quality of disclosures be tracked and publicly reported?

RECOMMENDATIONS FOR MS W

The National Quality Forum Safe Practice offers a model that institutions can use to develop their disclosure programs.[47] It calls for disclosure training of clinicians and having "disclosure coaches" available around the clock to provide just-in-time support for clinicians immediately prior to a disclosure. The coaching model recognizes that these conversations can be very challenging, that most clinicians have little experience with disclosure, and that careful planning and consultation with experts benefit the disclosure process. Whether these National Quality Forum recommendations are effective remains an open question for research.

After the first error, Ms W noted, "*I lost a lot of confidence in being able to trust my doctors. And I actually became quite frightened of things like any invasive procedure or getting an injection.*" The elephant in the room in many disclosure conversations is trust. Providers worry that disclosing too much about the error will diminish the patient's confidence in their clinical skills and damage the therapeutic relationship. Trainees may be particularly concerned about disclosure's effect on patient trust, as they may not fully trust their own emerging clinical skills.[54,81,82] Patients are also concerned about whether they can trust the professional's clinical competence, as well as their honesty and integrity. Yet patients may worry that voicing these concerns might offend the clinicians. Above all, fearing what they may hear, clinicians may hesitate to open Pandora's box of trust with patients.

Given trust's central role in the patient-physician relationship,[83,84] physicians should consider discussing trust explicitly with patients during disclosures. Ms W's physician might have said, "I know how important it is that patients trust their surgeon. I am confident I can safely remove the correct lesion on your nose but would understand if you would like another doctor to perform the second operation." When clinicians address trust directly, it demonstrates their awareness of the issue's importance and their commitment to repairing the patient-physician relationship to the extent possible.

Ms W's physician considered this error her "worst nightmare." Clinicians experience substantial emotional distress following errors, and institutional programs to support this distress are underdeveloped.[17,85,86] Clinicians may hesitate to access existing support programs because of em-

Table 2. Recent Developments in Disclosure

Institution/Organization	Development	Additional Comments
Veterans Health Administration	Lexington, Kentucky, Veterans Administration adopts policy of "extreme honesty" in 1987[77]; disclosure policy disseminated throughout Veterans Health Administration (VHA) in 2003	Policy updated January 18, 2008: VHA Directive 2008-002
COPIC	Develops "3Rs" program in 2000 to couple disclosure with no-fault compensation for selected patients[2]	COPIC is a private, physician-directed, Colorado malpractice insurer; West Virginia Mutual and ProMutual Group have adopted similar programs
The Joint Commission	Adds requirement to disclose "unanticipated outcomes" in 2001 to its accreditation standards for hospitals and health care organizations[78]	
University of Michigan Health System	Creates program in 2001 promoting disclosure and early offers of financial settlement[76]	Large academic health system; program available to all patients harmed by error regardless of severity
Australia	Disseminates "Open Disclosure" policy across Australia in 2003	Pilot data on effectiveness of program available[57]
Harvard University/CRICO	Develops, disseminates "When Things Go Wrong" disclosure policy (2006), providing disclosure coach training throughout Harvard system	http://www.rmf.harvard.edu/education-interventions/films/when-things-go-wrong/index.aspx
National Quality Forum	Releases "Safe Practice" on disclosure in 2006[47]	Updated practice published 2009.[79] Hospital-specific performance on safe practices available at http://www.leapfroggroup.org/cp
University of Illinois Medical Center at Chicago	Adopts Michigan-style disclosure-and-offer program in 2006[46,48]	"Patient Communication Consult Service" assists clinicians with disclosure, and "Care for the Care Giver" program supports clinicians following events
Stanford University	Launches "Process for the Early Assessment and Resolution of Loss" (PEARL) disclosure-and-offer program in 2007	Stanford's captive insurer has adjusted its claim review process to provide guidance on compensatory offers within 7 days of receiving the notice of event (J. Driver, JD; written communication, June 2009)

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barrassment, guilt, fear about confidentiality, denial of their distress, or unwillingness to take time away from work. It is important to address clinicians' emotions in advance of disclosures; distraught clinicians are poorly positioned to conduct a patient-centered discussion. Disclosures that are successful promote healing of the clinicians' and patients' emotions, while ineffective disclosures can do the opposite. Institutions should develop and strengthen systems for supporting clinicians after errors.[10]

For Ms W, not being able to talk with the trainee was " . . . a real lost opportunity for both of us." While most trainees report having been involved in errors, only a minority say they have disclosed errors to patients or received disclosure training.[53,81,87] Disclosure is the attending physician's responsibility; the attending physician is legally responsible for the patient's care and likely has more experience conducting difficult conversations with patients. However, removing trainees entirely from the disclosure process leaves them unprepared for this challenging task and, as in this example, deprives both trainees and patients of disclosure's healing potential. Training programs should ensure that their trainees have observed at least 1 error disclosure led by an attending physician and have practiced disclosure in a simulated setting.[88-90] Similarly, the trainee should understand the importance of incorporating the process of disclosure and continuing dialogue with the patient into the patient's ongoing care.

Patients like Ms W have an important role to play in the prevention and resolution of medical errors. National organizations encourage patients to take active steps to prevent medical errors in their care.[91] Patients are willing to undertake many of the recommended error prevention behaviors, such as asking what their medications are for, but are less comfortable with other recommendations, such as asking clinicians if they have washed their hands.[92] After errors, patients can also try to be as explicit as possible with their clinicians about their concerns, questions, and needs following the error.

Just as Ms W was a valuable source of information about the error, institutions should routinely seek patient (and family) input after errors. "*I was never given a mirror to see where the spot had been marked. If I had been, I certainly would have known right away that it was the wrong spot . . . I knew there was supposed to be a 'time out' where there is some coordination between the staff . . . and there was not coordination at the point to step back and say, 'Is this the spot? Does it look the same as in the record?'*" Some institutions are experimenting with involving patients in error analysis sessions, a development that should be encouraged.[93] By considering disclosure a quality improvement rather than a risk management activity, institutions strengthen their culture of transparency and patient safety.[47,58]

Ms W noted, "*Once you have something like this happen, you just see your health care through a different lens. And now that I'm getting older . . . I really have anxiety about what happens when I have another thing happen to me . . . I hope that people will realize that since this has happened to me, I'm going to need special handling.*" The developing momentum toward open disclosure in health care is admirable, but when will patients like Ms W routinely receive open and empathic disclosure when harmed by their medical care?

QUESTIONS AND DISCUSSION

QUESTION: How do you handle the word "mistake?"

DR GALLAGHER: We know that physicians (and lawyers) are split on whether and when to use the words "mistake" or "error." I think the prime concern is that the term "mistake" or "error" is provocative, and once patients hear it they will stop listening to the disclosure. But when they accurately reflect on what happened, I believe that using these words is an important part of transparency. Otherwise, the patient wonders, "Why won't the doctor just come right out and say what happened?" But I will acknowledge that many physicians and risk managers strongly believe that these terms are not helpful in disclosures.[3,11] It is a key issue we need to resolve.

QUESTION: What is the best way to teach the communication skills necessary for effective disclosures? Specifically, how might we use the simulation centers that are coming up all across the country to develop those skills?

DR GALLAGHER: Simulation is a very effective way to teach communication skills generally and disclosure in particular.[94-97] As with any communication skill, you need the opportunity to practice. The most common approach to disclosure training appears to be providing background lectures to medical students and more intensive training, such as simulation, to residents and attendings. One key dimension of disclosure simulation training is providing high-quality feedback to the participants. Without expert feedback, learners simply practice the wrong approach and don't improve. Therefore, the simulations should include an experienced disclosure coach who can watch learners, give them targeted feedback, and let them try again. That's the best way to learn these skills.

QUESTION: We took the patient's word that she had never been shown a mirror after the spot was circled. How do you proceed in a situation where a member of the team says, "No, I did it right. The patient might have been anxious."

DR GALLAGHER: It is very tricky. Disclosure is being increasingly recognized as an institutional responsibility, which includes conducting a thorough analysis to determine what took place. Sometimes the individuals directly involved in the case may not be the best persons to actually give the disclosure. Patients really want disclosures to come from their clinicians, and 95% of the time, that's appropriate. But sometimes it's not, either because the clinician does not agree with the results of the event analysis or the clinician's communication skills or emotional distress are such that you know that they're not going to do an effective job. In those circumstances, the harm caused by having that health care

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worker in the room outweighs any benefits, and it's better to have the medical director or someone else give the disclosure.

QUESTION: Often I've had difficulty understanding what the family or patient expects prior to a disclosure. What do you suggest doing to prepare for understanding those expectations prior to a disclosure meeting?

DR GALLAGHER: Sometimes it isn't possible to get a sense of the patient's expectations in advance of the initial disclosure conversation. Research does show what, in general, patients' expectations are, and this can help start disclosure conversations.[98] Moreover, using good communication skills to discern whether the patient understands what is being said can help in the moment.

For follow-up conversations, it's easier to figure out the patient's issues. One option when follow-up meetings are being scheduled is to have an administrative assistant ask the patient, "Can you tell me all the things you want to make sure Dr X addresses?" The patient can brainstorm about what's on his or her mind in a less threatening situation because the patient is not talking directly with the physician. Frequently, the patient's concerns are different from what you thought they would be. The only way to really find out is to ask.

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Perspective

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Malpractice Reform — Opportunities for Leadership by Health Care Institutions and Liability Insurers

Michelle M. Mello, J.D., Ph.D., and Thomas H. Gallagher, M.D.

In February 2010, the Illinois Supreme Court ruled that the state's cap on noneconomic damages in medical malpractice cases violated the Illinois constitution.[1] This development has contributed to growing pessimism about traditional approaches to medical liability reform. In some quarters, interest is shifting to innovative reforms that can be implemented by health care institutions and liability insurers without requiring changes in the law. These approaches provide a better balance between the interests of providers and those of patients and illuminate a path around the political gridlock over tort reform. They also afford opportunities for health care institutions and liability insurers to take the lead in reforming the processes for providing compensation for medical injuries.

Here, we focus on emerging models of disclosure of medical injuries and early resolution of cases ("disclosure and offer" programs). Other models of private reform, including mandatory binding arbitration and voluntary mediation, have reportedly had some success but have failed to become widespread. The market may be more receptive to disclosure-and-offer approaches, which link the compensation system to improvements in patient safety.

In general, private, institution-led reforms have many advantages. First, most of the reforms can be pursued without legislation. In some states, it is nearly impossible to effect liability reform because of political divisions fostered by powerful interest groups. In others, the legislature is dysfunctional and unable to accomplish major reform or is hamstrung by budgetary problems. Initial optimism that federal health care reform legislation would include major liability reform eventually faded, though the Obama administration has made a substantial commitment to supporting demonstration projects in which health care systems or states implement innovative reforms.[2]

Second, institutional reforms can be led by physician champions and other insiders, promoting buy-in from clinical and risk-management staff. Third, because most private approaches do not abridge legal remedies, they may be more palatable to consumer groups, trial-lawyer organizations, and patients. Fourth, private approaches can be tailored to each institution's unique culture, systems, and resources. Finally, institution-led approaches represent

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Policy Mechanisms for Encouraging Institutional Malpractice Reforms and Potential Benefits.

Policy Mechanism	Potential Benefits
Funding of rigorous evaluations of existing programs	Bolster the evidence base for particular reform models, reducing uncertainty and perceived risk for institutions
Federal and state funding for demonstration projects	Bolster the evidence base for particular reform models, including information about generalizability of anecdotal successes Encourage institutions to design and test new approaches Reduce the direct financial costs of implementing reforms
For institutions that implement reforms, provision of subsidized reinsurance or other mechanisms to limit the institution's potential financial losses	Reduce the financial risk of implementing reforms
Provision of "pay for performance"–type incentives for institutions that implement successful reforms	Provide financial incentives for implementing and evaluating reforms
Passage or strengthening of state laws that provide legal protection for disclosure, apology, and settlement statements	Reduce the legal risk associated with implementing disclosure-and-offer programs
Relaxation of reporting requirements to the National Practitioner Data Bank and state medical boards, or clarification that they do not apply to disclosure-and-offer program payments	Reduce perceived collateral adverse effects of agreeing to early settlement offers
Clarification that state insurance departments will look favorably on proposals for disclosure-and-offer programs or other modifications to claims-management processes	Reduce administrative barriers to adopting new approaches to insurance or claims management

a market solution governed by market forces. Insurers and health care organizations (and perhaps even clinicians and patients) can "vote with their feet," and successful programs can be expanded and replicated, while unsuccessful ones are discontinued.

The disclosure-and-offer approach has been implemented by a handful of hospital systems and liability insurers, building on an early experiment at the Veterans Affairs hospital in Lexington, Kentucky.[3] Three distinct models have emerged. All begin with an organizational policy of full disclosure of adverse events and training and support for clinicians to aid them in making disclosures. All share a general philosophy of risk management that holds that being candid about medical injuries, apologizing when appropriate, and providing for the patient's financial needs (in at least a limited way) through a quick, accessible process will eliminate the impetus for most patients or families to sue and will spur institutional learning and safety improvement. The models diverge in their specific approaches to compensation.

In what we call the "reimbursement model," the institution offers to reimburse the patient for some out-of-pocket expenses related to the injury and for "loss of time." The program has a predetermined limit on reimbursement (typically about $25,000 for expenses and $5,000 for loss of time), and reimbursement is offered without an investigation into possible provider negligence. Patients who accept the money do not waive their right to sue. However, injuries that are clearly due to substandard care, as well as fatal injuries and cases in which a claim has been filed or an attorney is involved, are excluded and handled through traditional claims processes. The best-known example of this model is the "3Rs" program operated by COPIC Insurance, a private, physician-directed medical liability company in Colorado.

The "early-settlement model," pioneered by the self-insured University of Michigan Health System,[4] is quite different. There are no preset limits on compensation. Compensation is not generally offered unless the institution, after an expedited investigation, determines that the care was inappropriate. The offer may include compensation for all elements of loss that are compensable in tort cases, including medical expenses, lost income, other economic losses, and "pain and suffering." To accept the money, patients must agree that it constitutes a final settlement, thus foreclosing a lawsuit. The early-settlement approach is applied to all injuries; there are no exclusion criteria.

The third model, proposed in scholarly work on the basis of the successful experience of several foreign countries, is health courts.[5] Patients are informed, at the time an injury is disclosed,

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that they can file a compensation claim with the provider or its insurer. A panel of experts, aided by decision guidelines, determines whether the injury was avoidable — a determination that turns on whether the injury would ordinarily have occurred if the care had been provided by the best specialist or an optimal health care system; the avoidability standard is more generous than the negligence standard. For avoidable injuries, the institution offers full recompense for economic losses plus an amount for pain and suffering according to a predetermined compensation schedule that is based on injury severity. Some health court proposals envision that patients who are dissatisfied with a decision could bring their case to a second administrative panel or judge provided by the state, with a limited right of judicial appeal.[5] Alternatively, in voluntary health court models (in which a state process has not been created through legislation), patients could reject the compensation offer and file a lawsuit, unless they had previously waived this right as a contractual condition of receiving care. Although health courts have not yet been adopted in the United States, President Barack Obama recently called for "demonstrations of alternatives to resolving medical malpractice disputes, including health courts."[2]

A key feature of all disclosure-and-offer models is that the information obtained from the investigation and resolution of injury cases is used to improve patient safety. All the countries with health courts maintain and analyze large national databases of medical injuries to identify dangerous conditions or processes and share that information with health care institutions.[5] Within U.S. institutions operating disclosure-and-offer programs, the analysis and sharing of data strengthen relationships between risk managers and patient-safety officers, facilitating the implementation of safety interventions. Liability insurers can use other strategies to promote safety, such as offering financial incentives to clinicians for completing disclosure training, following safe practices, and reporting incidents promptly to risk-management officials. Although all these measures can be pursued within traditional claims-management processes, disclosure-and-offer programs create structures and institutional commitments that enhance their effectiveness.

Nevertheless, institution-led malpractice reform has limitations. The development of local programs exacerbates the patchwork nature of compensation for medical injury, which originates from variations among juries and state tort reforms, and can cause inequities in compensation for patients with similar injuries. In addition, institutional innovations are harder to evaluate rigorously than are statewide reforms. More innovative reforms are riskier than more traditional types of reforms. Health courts have not been tested in the United States, and it is unclear to what extent the successes reported by pioneers of the reimbursement and early-settlement models would be generalizable to other institutions. A program's success would probably be affected by the particular organizational structure of the institution, the availability of resources, the institution's tolerance for risk, and the personalities of those involved in implementing the program. Furthermore, the fact that private reforms generally preserve legal remedies constrains their ability to limit litigation.

Institution-led reform may also be hampered by regulatory requirements. For example, state insurance departments, which regulate the management of malpractice claims, may be more permissive or less permissive in their attitudes toward disclosure-and-offer programs. The federal requirement that all claims payments be reported to the National Practitioner Data Bank may discourage physicians from agreeing to early settlements, though the requirement does not apply to reimbursement programs. Finally, leaving reform to private institutions may result in reforms that are driven more by financial benefits for hospitals than by considerations such as improved performance of the injury-compensation system or "doing the right thing" for patients.

Certain policy measures could stimulate more widespread adoption of private malpractice reforms (see table). This experimentation is not free of risk, but institutions should seize the opportunity to lead rather than wait for tort reform at the federal or state level. Their ingenuity, vision, and commitment to helping injured patients can improve a system that bedevils providers, patients, and policymakers alike.

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The Potential Health Effects of *Citizens United*

Lainie Rutkow, J.D., Ph.D., M.P.H., Jon S. Vernick, J.D., M.P.H., and Stephen P. Teret, J.D., M.P.H.

On January 21, 2010, the U.S. Supreme Court reached one of its most controversial decisions in years, with *Citizens United v. Federal Election Commission*.[1] The opinion overturned long-standing precedents that forbade corporations from using unlimited monies from their general funds for political speech — specifically, for advertisements supporting or opposing candidates for elected office, in the weeks and months before certain elections. Although it may not initially appear to concern health, *Citizens United* has important implications for health care providers and public health. The Court has effectively opened the financial floodgates to give corporations unprecedented influence over the election of the people who determine health policy.

Corporations are legal entities whose rights include the ability to sue and be sued, the power to initiate and sign contracts, and the ability to own property. In his dissenting opinion in *Citizens United*, Justice John Paul Stevens wrote that "corporations have no consciences, no beliefs, no feelings, no thoughts, no desires. Corporations help structure and facilitate the activities of human beings."[1] Although their rights are similar to those of people, corporations are creations of the state that receive legal protections to help individuals conduct business and generate profits.[2] With *Citizens United*, the Court has given corporations a powerful tool for promoting their interests, regardless of health or other consequences.

For decades, a patchwork of laws governed corporations' role in the electoral process. Before *Citizens United*, federal law forbade corporations from using their general funds to run advertisements advocating for or against a particular candidate within 30 days before a primary election or 60 days before a general election. In 1990, in *Austin v. Michigan Chamber of Commerce*, the Court explained the reasoning for these limitations, writing that "corporate wealth can unfairly influence elections when it is deployed in the form of independent expenditures" (see table).[3] With several new Supreme Court justices on the bench, the new decision overruled *Austin*, lifting the limits on corporate-funded political advertisements. The case has led to speculation that, at times, personal ideology rather than fidelity to precedent influences the Court's more divisive decisions.

The case originated when Citizens United, a nonprofit corporation, wanted to distribute its film *Hillary: The Movie* using video-on-demand technology during the 2008 presidential primaries. According to the Court, *Hillary* offered a "pejorative" portrayal of then-Senator Hillary Clinton (D-NY). To promote *Hillary*, Citizens United planned to run television advertisements. Lower courts prohibited it from doing so, finding that the plan conflicted with federal laws regulating corporations' political speech. The Supreme Court has now reversed these rulings, concluding that the advertisements were a form of speech protected by the First Amendment.[1]

Before *Citizens United*, corporations could finance political advertisements in advance of an election only through political action committees (PACs). Described by the Court as "burdensome" to create and "subject to extensive regulations," PACs are funded through voluntary contributions and must file frequent, detailed reports with the Federal Election Commission (FEC). Now, instead of relying on PACs' donated monies, corporations can draw directly from their own extensive resources to fund political advertisements before an election. *Citizens United* similarly expanded the rights of labor unions, but unions generally have less money than corporations for political activities.

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WPHP Disruptive Behavior
Policy and Procedure

Introduction

The intent of this policy and procedure is to delineate WPHP's role in assisting the medical staff and referral sources in appropriately managing disruptive (distressed) behavior in healthcare practitioners. The goal of this 5-step procedure is to define appropriate steps to be taken by the medical staff, define when WPHP will become formally involved, and to determine whether or not an underlying treatable illness exists. WPHP has a protocol for intervention, evaluation, treatment, and monitoring. WPHP asks that this procedure be followed preparatory to a formal referral to WPHP, although WPHP is willing to assist and advise in its implementation throughout the process.

WPHP will not become formally involved with the health professional in question unless and until the medical staff have exhausted due process provisions of their bylaws and stand ready to suspend privileges. At that critical juncture WPHP is able to provide support and monitoring with the full backing of the medical staff.

Definition

Disruptive Practitioner Behavior – A practitioner who has a pattern of being unable or unwilling to work with the health care team to such an extent that their behavior, through word or action, has the potential to interfere with quality health care.

Preamble

WPHP recommends a step-wise intervention process, which begins upon first incident of unacceptable behavior. Each level increases the obligation of the practitioner to adjust behavior. Inability to alter behavior to acceptable norms of professional interaction will prompt escalated levels of intervention.

WPHP proposes this model with the understanding that each case is unique and the medical staff requires latitude to address variation from case to case. For example, a level one intervention might be effective, yet be required again at some point in the future. In other circumstances, a single act may be sufficiently egregious as to warrant a higher level of intervention. Used in concert with the organization's bylaws, we believe this stepwise approach to be reasonable, fair, and productive of acceptable outcomes.

Level 1 "Informal Cup of Coffee" Intervention

Behavior that is out of character and not "egregious" may initially be approached by a peer, section chief, division head or chief of staff in what may be called a "cup of coffee" intervention focusing on a single issue or event. It is a respectful, non-judgmental sharing of what "I heard," "I saw," or "was reported" that did not seem consistent with the individual's usual behavior or character. The sole purpose of this intervention is to communicate that the behavior or performance was observed in hopes that the practitioner will exert professional self-regulation.

Level 2 Colleague Level

This meeting with the practitioner is a confidential, informal, discussion of the alleged behavior between the involved practitioner and supportive colleagues who represent the medical staff. WPHP recommends two to three respected, neutral colleagues participate with the identified practitioner. The issues are discussed confidentially in a collegial but direct way. Informal support, such as referral for therapy, a practice coach, etc. can be offered and discussed. It is made clear to the practitioner that the behavior

must stop. The practitioner is informed that confidentiality will cease if the behavior persists. A follow-up letter should be sent to the practitioner recapping the meeting content and agreements/expectations.

Level 3 Medical Staff Level

If the behavior persists, the third meeting is a non-confidential, formal meeting between the practitioner and a designated medical staff committee (e.g. Medical Executive Committee) which may include the colleagues involved in the previous meeting, medical staff leaders, and appropriate administrative and supervisory representatives. Medical staff must be mindful to adhere to their own bylaws as well as afford due process. The documented behavior is reviewed and, if appropriate, help is again offered. The practitioner is made aware that the behavior at issue must stop and that continued or recurrent disruptive behavior will prompt action. A follow-up certified letter is sent to document the meeting and subsequent expectations. The healthcare professional is advised that any further instances of behavioral disruption will result in a formal referral for evaluation and treatment and will be grounds for disciplinary action at the staff's discretion.

Level 4 WPHP Level

If the behavior persists, the designated committee or MEC arrange a meeting for referral. This meeting is a non-confidential, formal meeting that provides the practitioner with two choices: 1) be referred to WPHP and comply fully with their recommendations, or 2) face reportable action such as suspension. The practitioner should be informed that a suspension is reportable to the regulatory entity and the National Practitioner Data Bank after 30 days. If the practitioner accepts the referral to WPHP, the practitioner must agree to the following:

- Sign the appropriate consents for two-way communication between WPHP, the referral source and any collateral parties with whom WPHP may wish to speak.
- Release all paperwork regarding the incidents in question to WPHP.
- Contact WPHP (206-583-0127) within three (3) working days to schedule an appointment. The appointment must take place within ten (10) working days.
- Come off-line if recommended.
- Engage in a comprehensive evaluation and treatment if indicated, in addition to subsequent monitoring by WPHP.*
- Implement a behavioral monitoring contract with WPHP, if indicated, constructed in concert with the evaluation/treatment professionals and the referral source that includes complete compliance with any recommended monitoring.
- Accept WPHP-assigned workplace monitors and free flow of information between WPHP, the workplace monitors, and medical staff assigned to assist in the process.

*It is the preference of WPHP that practitioners be granted a medical leave of absence to attend any indicated evaluation or treatment.

Level 5 Disciplinary Level

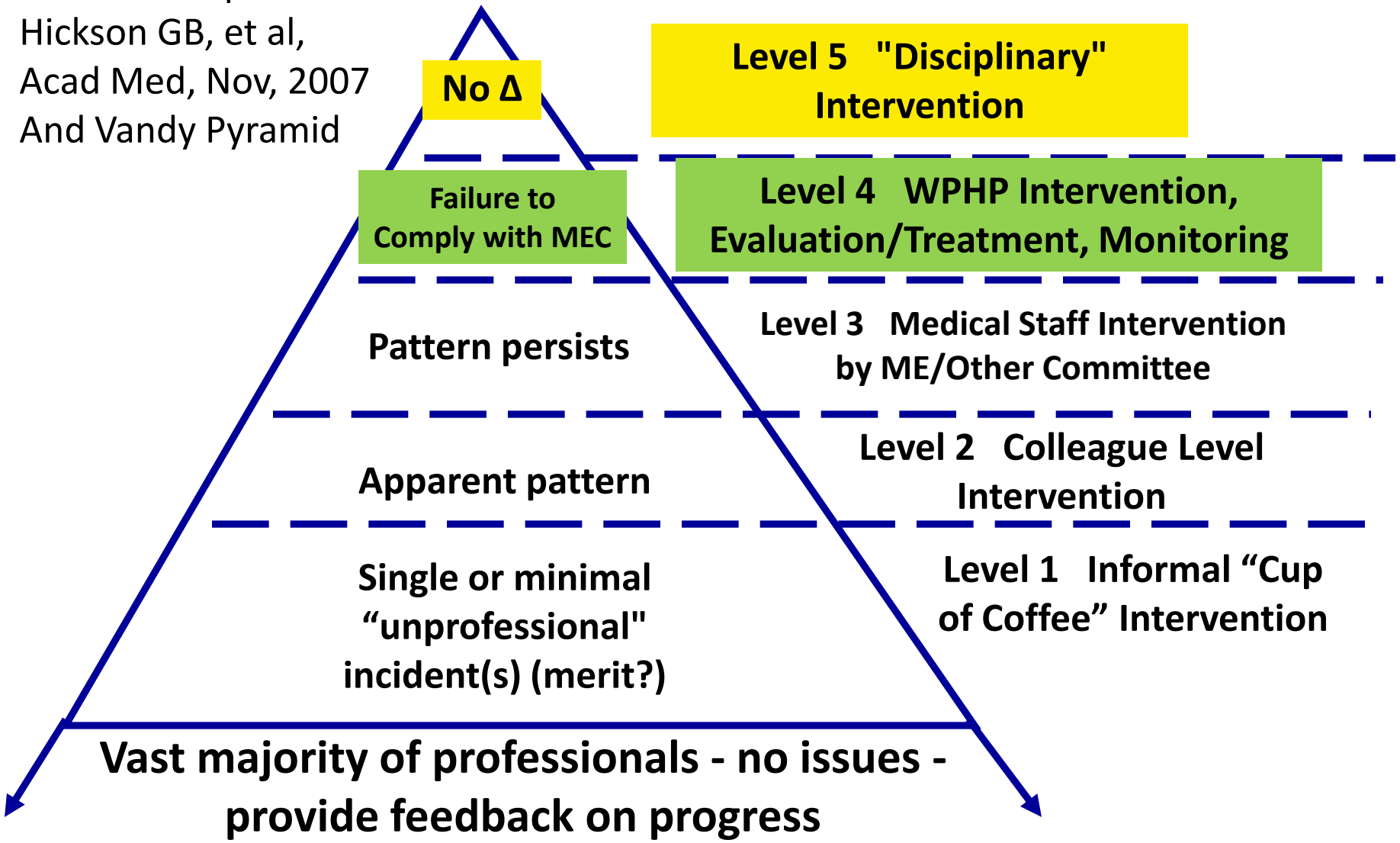
Practitioner's case is reported by WPHP or MEC to the appropriate regulatory entity.

NOTE:

1. **It is important that the medical staff follow its bylaws and consult with its attorney as necessary throughout this process.**

Promoting Professionalism Pyramid

WPHP – adapted from Hickson GB, et al, Acad Med, Nov, 2007 And Vandy Pyramid



As it stands, the American health care system is the most expensive in the world. Yet what do we have to show for it? The United States ranks approximately fiftieth in the world for life expectancy.[1] A study published by the *Journal of the American Medical Association* in 2000 concluded that our health care system itself is the third-leading cause of death in the country. This study took into account only hospitalized patients, but it covered a host of causes, including errors, unnecessary surgeries, infections, and the side effects of properly prescribed drugs approved by the Food and Drug Administration.[2] The study estimated that there are 225,000 patient deaths per year. Only the fast-food and cigarette industries can compete.[3] In our current health care system, there is very little care and almost no attention to health. I would go so far as to say that we don't have a health care system; we have an illness management system. How did it come to this?

In 1910, the Flexner report discredited alternative medical schools, while praising allopathic medical schools for being more regimented. As a result of that report, many alternative schools closed, the diversity of medical education was drastically reduced, and allopathic medicine became the dominant form of practice in the United States. Additionally, access to medical education was less available to women, people of color and low-income individuals. Flexner was right: allopathic medicine is more regimented than the alternatives. But that doesn't mean it's more scientific. The majority of both allopathic and alternative methods are supported by very little evidence that is considered adequate.

Allopathic medicine is more regimented than the alternatives because it is problem-focused, not person-focused. The average allopathic medical visit lasts only ten minutes and is designed to find and label the "problem." The doctor is supposed to do this by navigating the mass of data that is the typical patient history. Once the problem is discovered, it is interrogated and documented, and the appropriate part of the patient is examined. The visit commonly ends with the writing of a prescription or the ordering of a test. Oftentimes, insurers requirements mean doctors spend more time charting about the patients than looking after the patients themselves.

This problem-focused approach treats doctors as gunslingers and illness as their enemies. The gunslinger approach works well if the doctor has clear and specific targets. It works best on acute problems like a broken leg, an acute stroke, or meningitis. Near-miraculous allopathic inventions, such as interventional techniques and drugs, have

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[1] www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html. Accessed December 25, 2012.

[2] Starfield B. "Is US health really the best in the world?" *JAMA*. 2000;284(4):483-5.

[3] Poor diet and physical inactivity accounting for 400,000 deaths or 16.6% of total deaths in the US.
Mokdad, Ali H., Marks, James S. and Stroup Donna F. et. al. Actual Causes of Death in the United States, 2000. JAMA. 2004;291:1238-1245. Accessed December 25, 2012.
Cigarette industries: Based on CDC data:
During 2000-2004, an estimated 443,000 persons in the United States died prematurely each year as a result of smoking or exposure to secondhand smoke. www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm. Accessed December 25

improved our treatment of acute illnesses and injuries. Nevertheless, problems arise, when the same model of care is used to treat chronic conditions.

Integrative Medicine (IM) looks at doctors as detectives rather than gunslingers. It asks more questions about context of an illness, is focused on the whole person, and sees health as a positive attribute that the doctor and patient strive towards in partnership. Its initial interventions include such things as careful nutritional advice, attention to the microbiome, the use of mind-body techniques to manage stress, herbs and supplements, and inter-professional collaborations with other disciplines. The IM approach works better for the majority of the population and for chronic illnesses. It is also less costly than the allopathic approach. But the major difference between the two is the risks involved in practicing each. In the words of Hippocrates, we should, first, "do no harm." Remember the 225,000 patient deaths per year? Our current health care system, an allopathic one, constantly causes harm. Despite this, we have supported it for a hundred years.

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Misuses and Misunderstandings of Boundary Theory in Clinical and Regulatory Settings

Thomas G. Gutheil, M.D., and Glen O. Gabbard, M.D.

Objective: This paper outlines a number of misapplications of boundary theory in both regulatory settings and clinical situations. Method: The authors review clinical vignettes that illustrate the difference between boundary crossings, which lead to productive work in psychotherapy, and boundary violations, which are harmful to the patient and exploit the patient's vulnerable position. They also discuss developments in the field that have led to an excessively rigid and defensive posture on the part of some clinicians that may lead to less than optimal psychiatric treatment. They survey recent developments in the wording of state statutes that broadly define sexual misconduct in psychotherapy. Results: This review of the current status of boundary theory in both the law and clinical practice suggests that an overreaction has occurred that requires correction. Conclusions: The critical role of context must be considered whenever a boundary problem has been alleged, and boundaries must be regarded as flexible *standards of good practice rather than lists of generically forbidden behavior.*

(Am J Psychiatry 1998; 155:409–414)

A 6-year-old boy kisses a girl in his first-grade class on the cheek. He is summarily suspended from school for sexual harassment. The media have a field day discussing the excesses of the sexual harassment construct. The school is embarrassed. The boy is reinstated. A fundamentally sound principle designed to prevent the encroachment of others on one's personal space and to protect the individual from obnoxious and predatory behavior has been stretched to an absurd extreme.

This recent news story reminds us that when pendulums begin to swing, they commonly swing too far. A similar trend can be observed in the area of professional boundary violations within the practice of clinical psychiatry. In the last decade the mental health professions have experienced a progressive raising of consciousness about the issue of professional boundaries. A series of contributions from our own work (1–6) and that of others (7–9) has demonstrated how the violation of professional boundaries by psychiatrists and other mental health professionals may cause harm to patients while also undermining effective treatment. Amid this laudable interdisciplinary heightening of awareness, we have also observed a perhaps predictable overreaction to boundary concerns and an associated misapplication of the underlying principles. While such excesses are often proffered as indicia of patient protection, the perversion of boundary theory may place professionals at risk for undeserved sanctions and may potentially harm patients themselves by frightening the professionals into rigidity in therapeutic interactions. This extreme position is captured by a cartoon that shows a male patient putting forth his hand for a handshake with his female therapist: the latter looks disdainfully at the outstretched hand and sneers, "Nice try!"

Much of the current concern about professional boundaries has grown out of a wish to prevent sexual misconduct by clinicians by identifying milder nonsexual boundary violations as possible way stations on a "slippery slope" toward frank sexual contact. Clinical observations have taught us that many boundary transgressions that do not involve erotic touch nevertheless may be destructive to the treatment process and to the patient. Meanwhile, forensic practitioners have observed a shift in misconduct litigation from cases of overt sexual intercourse to cases of "pure" boundary violations: "pure" in the sense that the only violations that were alleged fell short of sexual intercourse (3). Plaintiffs' attorneys have also noted that many malpractice insurance carriers will not provide coverage for sexual misconduct but may cover various types of transference or countertransference mismanagement. In addition to the civil litigation on these issues that alleges traditional malpractice, licensing and registration boards in medicine and the behavioral sciences, as well as ethics committees of professional organizations, have also become involved in patient complaints about alleged nonsexual boundary violations.

In this communication we will describe some of the

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significant misuses and misunderstandings that have occurred in the name of attention to professional boundary concerns. We will also propose a more rational conceptual framework within which to consider boundaries. Although we are primarily focusing on psychotherapy, we will also note appropriate modifications for other psychiatric treatment modalities. Our goal is to hasten the arrival of the pendulum to the midpoint between the extremes of boundaryless clinical practice and rigid overreaction.

FUNDAMENTAL PRINCIPLES

A boundary may parsimoniously be defined as the "edge" of appropriate behavior (1). This edge resists sharp definition not only because of the diversity of psychotherapeutic approaches, but also because within any one school of thought, most clinicians would agree that the therapist must attempt to tailor the treatment strategy to the particular requirements of the individual patient. The establishment of clear boundaries is designed to create an atmosphere of safety and predictability within which the treatment can thrive. Professional boundaries involving such elements as the absence of sexual contact, the arrangements for the fee payment, the length of sessions, and the relative asymmetry of self-disclosure are not simply an arbitrary set of rules designed to make it easier to discipline deviant clinicians. Nor are they intended to create a remote and rigid way of relating between therapist and patient. On the contrary, *external* boundaries are established so that *psychological* boundaries can be crossed through a variety of mechanisms common to psychotherapy, including empathy, projection, introjection, identification, projective identification (5), and the interpretation of transference. Langs's concept of the frame (10) and Winnicott's notion of the "holding environment" (11) address similar concerns.

We have suggested that boundary transgressions can be divided into two broad categories (1). The first is a "boundary crossing," a benign variant where the ultimate effect of the deviation from the usual verbal behavior may be to advance the therapy in a constructive way that does not harm the patient. (The use of the term "boundary crossing" in its technical sense was suggested by Axel Hoffer, M.D., and Douglas Ingram, M.D., in personal communications.) Some of these may be fully appropriate human responses to unusual events that might involve physical contact. A patient stumbled as she was leaving the office and fell to the floor. The therapist helped the patient up and made sure that she was all right. A patient entered her therapist's office and announced that she had just received news that her son had died. The patient reached out to embrace the therapist, and the therapist accepted the embrace as the patient sobbed. A failure to respond in a human way in such situations would very likely devastate the patient and might even lead to a premature interruption of the therapy.

Another variant of a boundary crossing is the countertransference enactment that is largely unconscious and occurs spontaneously in the course of the therapy (12–15). While these may be departures from the usual mode of therapeutic interaction, they are subsequently discussed and explored in a way that is productive for the treatment process. For example, at the end of a long and frustrating session, a therapist felt as though nothing she had said had been helpful. She had been preoccupied with the fact that her own mother was ill, and she had not been as available to the patient as usual. As the therapist and patient got up from their chairs, the patient asked, "So where are you going next week?" Without thinking, the therapist responded, "I'm going to visit my mother in Colorado. She's very ill." The patient said, "Oh, I'm sorry," and left the office looking worried. The therapist instantly recognized that she had revealed information that might have burdened the patient with her own problems. As she reflected on her enactment, she recognized that she had been feeling guilty about not having been very helpful because she was so preoccupied and that she had unconsciously tried to gain some sort of absolution or forgiveness from the patient by explaining the situation to him.

After her 1-week absence, the therapist brought up what had happened at the end of the session with the patient and explained that she probably should not have burdened him with the information she offered. She went on to suggest that they might beneficially explore his reactions to it. In the course of sharing some of his thoughts about what had happened, the patient noted that his mother had always confided her problems to him, and he thought something like that was repeating itself in the therapeutic relationship. In this instance no lasting harm was done to the patient, and the event turned out to be a useful focus for further exploration. An important factor that led this enactment to be constructive is that it was *discussible* by the therapist and patient.

The second broad category is the "boundary violation," when the transgression is clearly harmful to or exploitative of the patient. In contrast to the boundary crossing, the boundary violation is usually not productively discussed by the therapist and patient and may also be part of a repetitive practice. The harm may range from wasting time and therapeutic opportunity to inflicting severe trauma. Examples include the therapist who hugs the patient at the end of each session and tells him or her "I love you," the therapist who asks the patient to pick up his or her dry cleaning, the repeated disclosure of the therapist's own personal problems in a way that burdens the patient, and of course, overt sexual contacts.

THE IMPORTANCE OF CONTEXT

A significant challenge to forensic experts consulting on such matters is often the distinction between a boundary crossing and a boundary violation. In addi-

tion to the aforementioned issue of whether or not the transgression is discussible, another helpful differentiating factor is *context*.

Thinking about boundaries can lead one to an absurd end point, unless one understands the critical role of the context in which behavior occurs (1). The context may be constituted by the treater's professional ideology, the presence or nature of informed consent by the patient, the point in the therapy at which behavior occurs, the respective cultures of the dyad, and such environmental factors as whether therapy occurs in a small town or in an urban center and whether public transportation is available. For example, a therapist who gives a patient a ride home in a blizzard might be judged differently, depending on whether the therapy occurs in a prairie town or a major city with a subway system, whether the patient feels coerced by the therapist to accept the ride, and whether the therapist also gives the patient rides when the weather is mild.

During the era of extended inpatient treatment, hospital therapists traditionally visited patients in the shops where therapeutic activities were going on and had conversations with their patients during leisurely walks on the hospital grounds. Many a shy patient with schizophrenia was far better able to communicate in the context of motion and open space than in the felt intimacy and imprisonment of an office. In most hospital settings today, the therapeutic culture is very different. Therapists and patients have only a short time to get acquainted (and thus to know each other's motives and intentions). Hence, taking a walk with a patient will likely be seen as a potential boundary problem, and visiting an activity group as an invasion of privacy.

Or consider this example in which cultural differences, timing, and transference combined to create a context for an action felt as a boundary transgression by the patient:

> In his native Vienna an analyst had courteously helped female patients put on and take off their overcoats. This was part of everyday politeness, and he would have been seen as rude had he abstained from this ritual. Upon moving to the Midwest he began the analysis of a young woman in early September. By the time cold weather began, the patient, a native Midwesterner, had developed erotic feelings toward the analyst, felt exquisitely embarrassed about them, and had not yet plucked up the courage to reveal them. On the first cold day of winter she experienced his swift advance to help her take off her coat as if he were about to disrobe her. Her sullen awkwardness signaled trouble to the analyst, who asked her what had disturbed her. She mumbled that she was not used to men taking her coat off. While it would still be a while before a full examination of her fear of (and wish for) intimacy would become possible, he elected in the meantime not to repeat his polite action. The analysis proceeded, but in today's world and with a patient more ill and contentious than this one, this analyst's behavior might well be misconstrued by overzealous fact finders as an inappropriate violation of a boundary.

In this situation a completely benign act of politeness was perceived *subjectively* by the patient as a potentially exploitative boundary violation, in part because of the stage of the treatment. This latter issue, as noted, represents a relevant context to aid in distinguishing the impact of a behavior from its intent.

The matter of context is all too often disregarded by fact finders and decision makers in this area, although it is essential to determine, inter alia, whether a specific behavior represents a boundary crossing or a boundary violation; indeed, the identical behavior may constitute either a boundary crossing or a boundary violation, depending *entirely* on the context in which it occurs.

In the following example, the context omitted from consideration was the treater's task and discipline:

> A female case manager (a community mental health center staff member given the responsibility of coordinating care and rendering practical assistance to patients) took many trips with a female patient to necessary appointments, accompanied the patient's family to the beach with her own family to encourage socialization and to model parenting, and performed many other out-of-office activities. The patient, a paranoid young woman, formed a strong attachment to the case manager and became furious when the relationship had to end because of the latter's pregnancy. At that point she persuaded her parents to bring an ethics violation complaint against her former helper. In subsequent litigation, no evidence emerged that the patient had been exploited or harmed in any way. But the regulating board hearing the case held the case manager to the standard of a psychoanalyst as to what constituted professional boundaries.

Since case management has always been a far more hands-on role than classical psychoanalysis or even psychotherapy, the preceding use of the wrong yardstick appears to reflect a fixed and mechanistic view of boundary questions; yet such misapplications are not uncommon in civil litigation, where the idea of an absolute boundary is appealing to plaintiffs' attorneys seeking a clear standard.

A therapist faced with deciding whether to call or visit a patient with a serious medical illness confined to a general hospital must use carefully considered clinical judgment. He or she would have to weigh the humanitarian benefits of a visit to the hospital against the potential for the patient to react with feelings of exposure and intrusion. Here the context might depend on the patient's history, the seriousness of the illness, the nature of the therapeutic alliance, and the patient's preferences. Obviously, a frank discussion between therapist and patient about the pros and cons of such a visit would be of considerable assistance in resolving the therapist's dilemma.

Even among professionals of similar disciplines, the task may vary widely. As we have noted previously (1), a behavior therapist assisting an agoraphobic patient through the use of in vivo exposure may drive the patient to a shopping mall to encounter the feared situation. A clinician engaged in psychoanalytic psychotherapy would be in serious need of supervision if similar activities were going on. Even within psychodynamic therapy, however, the appropriate frame varies

from patient to patient (5, 16, 17). Certain patients require greater degrees of verbal activity or therapeutic self-disclosure for them to feel engaged in a treatment process. Also, some therapists may have a more self-revelatory style than others. The therapeutic frame is necessarily constructed by the two subjectivities that meet in the consulting room. Hence, it is a collaborative construction based on the particular characteristics of a specific dyad. A senior male therapist treating a 19-year-old young man who finds it difficult to talk may use conversations about sports to engage the patient at a level where he feels comfortable about relating to the therapist. In the course of this conversation, the therapist may reveal a great deal about his interests in sports, his preferences for a certain team over another, and his activities during the past weekend (if he happened to attend a sporting event). While he is self-disclosing, he is also adapting the frame to connect with the patient in a way that facilitates a therapeutic alliance.

One of the most frequent misuses of the concept of boundaries revolves around self-disclosure. Contributions in the literature (18–20) have stressed that therapists are disclosing aspects of themselves every time they open their mouths. Indeed, the visual cues available in the therapist's office speak abundantly of the character of the occupant through the order or disorder of the office contents, the expression of taste (or lack of it) in the decor, and the comfort or discomfort of the furnishings. While these disclosures affect first impressions and generally fade in importance under the influence of getting better acquainted and of transference, their impact illustrates the impossibility of avoiding being known.

The boundary issue is not whether self-disclosure occurs or does not occur. Rather, the key issue is *what* the therapist self-discloses and whether the therapist burdens the patient with personal problems in a manner that reverses the roles in the dyad. For the therapist to acknowledge his or her anger at the patient can be useful in advancing the therapy. For example, a hospitalized patient lied to her therapist and the nursing staff about possessing a razor blade and delighted in having won their trust only to flaunt her power to deceive them. The therapist felt betrayed and hopeless as to his ability to help someone so deceitful and mean. He was encouraged by his supervisor to see his patient briefly at their next scheduled meeting to inform her that he was too angry to be helpful to her for the moment and that he would need some time to think about what had happened and whether he would be able to go on being her therapist. Such a period of reflection allowed him to explore his emotional reaction, while affording the patient an opportunity (with the help of the skilled nursing staff) to consider the consequences of her behavior.

There are, of course, other countertransference feelings that therapists should not disclose to their patients. It is rarely useful to say to a patient, "I have sexual feelings for you" (21). Saying "I hate you" is also unlikely to be helpful. Nevertheless, the therapist might well examine with the patient certain interactions that are likely to lead to hateful or sexual feelings. Here again, context and the manner of disclosure are critically important.

LICENSING AND REGISTRATION BOARD CASES

Although ostensibly concerned with general fitness to practice, boards of registration are often recipients of specific complaints couched in terms of boundary issues. Those issues can be remarkably trivial and curious.

> During a visit with her internist, a patient reported having had a number of recent losses through deaths of close family members. Discussion of these losses led her to burst into intense sobbing. Later that evening the internist called the patient at home to see if she was all right. She reassured him that she was, but she later reported him to her state licensing board for the alleged boundary violation of calling her at home.

Boards themselves vary to a striking degree in their rigor, flexibility, and, regrettably, punitive attitudes toward the clinicians they license. The following excerpt of sworn testimony at a licensing board hearing in a Midwestern state captures another variation of an extreme position on nonsexual boundaries:

> *Q [board prosecutor]:* Did you also find in the testimony and the records that [the patient] attended the same church [the accused doctor] did?
>
> *A [psychiatric expert witness:]:* Yes.
>
> *Q:* Do you recall how [the patient] became acquainted with that church?
>
> *A:* Yes, I believe [the doctor] gave the patient *a list of churches*, including his own [emphasis added; other testimony revealed that the patient had asked for referral to "noncoercive" local churches].
>
> *Q:* If [the doctor] provided a list of four or five churches to [the patient], one of them was his own and the patient knew that, which church would this patient likely choose?
>
> *Defense attorney:* Object, calls for speculation.
>
> *Judge:* I will sustain that. You can ask him if he has got an opinion on that.
>
> *Q:* In your opinion, [doctor serving as expert witness], as a psychiatrist, if a psychiatrist provided a list of four or five churches to a patient and that patient was having idealizing transference with that psychiatrist, one of those churches was the psychiatrist's and the patient knew that, in your opinion, which church *would* the patient choose?
>
> *A:* In my opinion, it *would be likely* that the patient *would be influenced* to go to the church that the psychiatrist recommended, that the psychiatrist was going to. [For these and all the following subjunctives, emphasis was added.]
>
> *Q:* And why *would* a patient do that?
>
> *A:* Because the patient *would trust* in the psychiatrist's judgment, *would want* to be close to the psychiatrist, *would want* to do what the psychiatrist does or recommends.
>
> *Q:* Was it within the minimum standard of care in the late 1980s for [the doctor] to recommend his own church to [the patient]? [Note that in this jurisdiction the licensing board standard is the extreme position, "minimum standard of care," rather than the more familiar "average reasonable care" of civil litigation.]

A: No.

Q: Why not?

A: Well, first of all, I don't think the psychiatrist's job or duty is to recommend churches to patients. There are others who can do that. [Note here that the situation is one where the patient asked and the doctor responded, rather than whether recommending churches is a doctor's *duty*, as this witness's testimony implies.] Second of all, it *would increase the likelihood* that the patient *would be* in a social interaction with the psychiatrist and *would provide* an opportunity that *would be ripe* for all kinds of boundary problems, boundary blurrings, and boundary violations.

Q: Can you describe some of those boundary blurrings that occur?

A: They *could be* sitting next to each other in the church. They *could be* involved in church activities together. The psychiatrist and his own family *might be involved* with the patient and his family. There *would just be an increase in the likelihood* of significant social interaction between them.

None of the preceding colloquy establishes how the patient would be realistically exploited by the doctor who is answering the patient's request for the names of churches. Instead, all of the preceding subjunctives posit a domino theory or slippery slope of possibilities, as if the church referral were a kind of quicksand within which the inextricably trapped doctor and patient would be forced to cross boundaries, unable to make other choices (e.g., going to another of the five churches). Disregarding the fact that no literature supports the claim that such church referral is below the minimum standard of care, we note that the late 1980s, the period referred to in the preceding testimony, was indeed the time that professional awareness of nonsexual boundary issues was first appearing in professional journals. Ironically, that same era marked psychiatry's dawning awareness of the importance of religion and spirituality in patients' lives. One "might" conclude that the speculative hypotheticals in the preceding excerpt are too gossamer a footing on which to place the weight of a physician's licensure and future career in a licensing board complaint.

This testimony also reflects the common confusion between boundary violations and chance extratherapeutic contacts. Therapists who have consulted us have expressed concern that they will be accused of violating boundaries if they run into their patients in a club, at a theater production, at the gym, or in a social gathering. Such chance meetings are, of course, inevitable, especially in small towns (although even in large cities certain therapists and patients find that their paths cross frequently because of common interests). The only significant risk of a boundary violation in such cases is if the therapist openly acknowledges that he or she is treating the patient and thereby breaks confidentiality. In most cases, the therapist can handle the situation appropriately by following Karl Menninger's dictum "When in doubt, be human." These encounters can be discussed later in the therapy in terms of their meaning to the patient; indeed, it is just such discussion that preserves the therapeutic process despite the encounter. Only *planned* meetings in a motel, a restaurant, or similar settings for purposes that in no way relate to the therapy are true boundary violations.

STATE STATUTES AIMED AT REDUCING BOUNDARY VIOLATIONS

In sincere efforts to provide guidance for clinicians, some states have promulgated statutory or regulatory advisories on boundary issues. These are subject to the same mechanistic flaws as the previous contexts. Consider a recently passed Rhode Island civil law that defines "sexual contact" as various forms of intercourse, sustained kissing, fondling, and the following:

> Exhibition by the MHP [mental health professional] in view of the patient or former patient of the MHP's genital area, groin, inner thigh, buttocks, or breast; voyeurism by the MHP in the form of viewing the patient's or former patient's genital area, groin, inner thigh, buttocks, or breast. The Act provides a civil cause of action against any MHP who engages in conduct as defined in the chapter. (22)

This broadened definition of sexual contact appears to open a hornet's nest of confusion. With women's skirts routinely above the knee, any time a female therapist *or* female patient crosses her legs, she exposes her inner thigh to the other party. Also, many male *and* female patients appear at therapy wearing shorts. Therapists would be forced into maintaining rigid and unswerving eye contact in a way that would totally constrict their free-floating attention and free-floating responsiveness to subtle enactments within the patient-therapist field. For psychodynamic therapy to be effective, therapists must immerse themselves in the experience of the patient without feeling undue restrictions regarding where they may look or how they might feel or think. Patients who characteristically evoke erotic reactions in others because of the way they behave, look, dress, talk, or move will inevitably evoke similar reactions in the therapist. This countertransference identification may lead the therapist to think about the patient in sexual terms. Like any other transference-countertransference interaction, the meaning of this erotic tension must be explored and understood to help the patient in other relationships outside the therapy.

Freedom of thought is necessary for the therapist's achievement of an optimal state of effectiveness. Restrictions on where the therapist looks, how the therapist feels, or what the therapist thinks are destructive to the process. When regulatory laws define "sexual contact" so broadly that they include looking at the patient's thigh, things have gone too far.

A similar problem has arisen in regard to restrictions on verbal discourse. For example, a Minnesota medical licensing board regulation (which has the force of law) defines grounds for disciplinary action to include "Engaging in conduct with a patient which is sexual or may reasonably be interpreted by the patient as sexual,

or in *any verbal behavior which is seductive or sexually demeaning to a patient*" [emphasis added] (23, p. 246).

This wording places in jeopardy such basic psychiatric and psychotherapeutic procedures as taking a sexual history, exploring the patient's sexual fantasy life, or understanding erotic transference. If a clinician makes a neutral comment, for example, that is interpreted as sexual by the patient, this perception is an important component of the patient's transference that needs to be explored. The problem with this kind of regulation is that a transference perception becomes reified into a fact for legal purposes. Casting this broad a net may create such anxiety in therapists that they systematically avoid discussions of a sexual nature with their patients. Many patients have problems in the area of sexuality, and most have some difficulty in bringing them up in treatment. If a patient senses that the therapist becomes distressed when sexual issues are raised, the patient may feel that his or her sexuality is indeed too disgusting or shameful for open discussion (24). The therapist may be realistically concerned that exploration of any sexual topic about which the patient is conflicted may result in that patient's feeling demeaned and therefore violated (not to mention aroused).

RECOMMENDATIONS

On the basis of the foregoing, it is clear that any efforts that hasten the boundary pendulum's arrival at a rational midpoint are welcome. In addition to openly discussing the issue as we have done, the following approaches might hasten a return to reason.

1. Statutes and regulations designed to protect patients should address the problem of the critical role of context in determining when a violation has occurred. Use of mechanistic checklists should be replaced by thoughtful examination of the boundary issues on a case-by-case basis—a procedure that courts and licensing boards have long performed to the point of complete familiarity.

2. Expert witnesses should familiarize themselves with the complexity of boundary issues in order to present ethical testimony that does justice to the variability and context dependence of the standard of care.

3. Educators and supervisors should explain the role of boundaries in terms of protection of patients and of the therapeutic frame, rather than presenting boundary lists as compendia of generically forbidden behavior. Ethics must be taught in the context of clinical concepts such as neutrality, therapeutic alliance, transference, countertransference, enactment, and so forth (25).

4. Ethics committees should similarly look with flexible standards at the critical question of context to assess the reality of exploitation or harm, rather than using lists. While concrete harm may be hard to demonstrate in all cases, guidelines aim at decreasing situations of *potential* harm.

5. Finally, we must recognize that clinical psychiatric practice is as much an art as a science. Our primary tools are ourselves. As such, we are imperfect and often need to flounder a bit before we strike the optimal balance between intimacy and distance that is favorable for a particular patient and a particular therapist at a particular time in treatment.

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The Concept of Boundaries in Clinical Practice: Theoretical and Risk-Management Dimensions

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The authors systematically examine the concept of boundaries and boundary violations in clinical practice, particularly as they relate to recent sexual misconduct litigation. They selectively review the literature on the subject and identify critical areas that require explication in terms of harmful versus nonharmful boundary issues short of sexual misconduct. These areas include role; time; place and space; money; gifts, services, and related matters; clothing; language; self-disclosure and related matters; and physical contact. While broad guidelines are helpful, the specific impact of a particular boundary crossing can only be assessed by careful attention to the clinical context. Heightened awareness of the concepts of boundaries, boundary crossings, and boundary violations will both improve patient care and contribute to effective risk management.

(Am J Psychiatry 1993; 150:188–196)

> Role boundaries may be crisp or flexible or fuzzy, depending on the role under consideration and on the cultural climate.
>
> —Ingram (1)

The concept of boundaries, particularly in the sense of boundary crossings and boundary violations, has come under increased scrutiny in relation to the wave of sexual misconduct cases (2) arising in litigation, ethics committee hearings, and complaints to boards of licensure. Like many concepts in psychotherapy, such as "therapy," "transference," and "alliance," the term proves slippery on closer observation. The literature tends to focus on patient-therapist sexual misconduct (3) as an extreme violation and not on the wide variety of lesser and more complex boundary crossings, many of which are, at first glance, less obvious but pose difficulties of their own for clinicians.

Clinicians tend to feel that they understand the concept of boundaries instinctively, but using it in practice or explaining it to others is often challenging. This latter problem is rendered more difficult by the tendency of the legal system, particularly plaintiffs' attorneys, to apply it mechanistically: any boundary crossing is bad, wrong, and harmful. Empirical evidence suggests that boundary violations frequently accompany or precede sexual misconduct (2, 4, 5), but the violations themselves do not always constitute malpractice or misconduct or even bad technique. However, modern clinicians should be aware of three principles that govern the relationship among boundaries, boundary crossings, boundary violations, and sexual misconduct.

First, *sexual misconduct usually begins with relatively minor boundary violations,* which often show a crescendo pattern of increasing intrusion into the patient's space that culminates in sexual contact. A direct shift from talking to intercourse is quite rare; the "slippery slope" is the characteristic scenario. As Gabbard (4) and Simon (6) have pointed out, a common sequence involves a transition from last-name to first-name basis; then personal conversation intruding on the clinical work; then some body contact (e.g., pats on the shoulder, massages, progressing to hugs); then trips outside the office; then sessions during lunch, sometimes with alcoholic beverages; then dinner; then movies or other social events; and finally sexual intercourse.

Second, *not all boundary crossings or even boundary violations lead to or represent evidence of sexual misconduct.* A clear boundary violation from one ideological perspective may be standard professional practice from another. For example, the so-called "Christian psychiatry movement" might condone the therapist's attendance at a church service with one or more patients, and various group therapeutic approaches or therapeutic communities may involve inherent boundary violations, as when some behaviorist schools permit hiring patients in therapy to do work in the treatment

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setting. Bad training, sloppy practice, lapses of judgment, idiosyncratic treatment philosophies, regional variations, and social and cultural conditioning may all be reflected in behavior that violates boundaries but that may not necessarily lead to sexual misconduct, be harmful, or deviate from the relevant standard of care.

Third, despite this complexity, *fact finders*—civil or criminal juries, judges, ethics committees of professional organizations, or state licensing boards—*often believe that the presence of boundary violations (or even crossings) is presumptive evidence of, or corroborates allegations of, sexual misconduct.*

To summarize the foregoing more concisely, albeit metaphorically, smoke usually leads to fire; one can, however, find smoke where there is no fire, and yet fact finders may assume that where there's smoke, there's fire. This metaphor is not trivial. In a notorious Massachusetts case (in which the doctor accused of sexual misconduct was eventually exonerated), the Board of Registration in Medicine, the state licensing authority, noted in the course of the process, "There was an undisputed level of intimacy between the two [patient and doctor] that supports the inference of sexual relations" (transcript of board proceedings, citation withheld). In its language here, the board clearly articulated its "inference" of fire from the "undisputed" presence of smoke. Moreover, recent court decisions suggest a trend toward findings of liability for boundary violations even in the absence of sexual contact (7). On this basis, the risk-management value of avoiding even the appearance of boundary violations should be self-evident.

This communication has three goals: 1) to review the subject in order to define, describe, and illustrate the range of boundary issues, 2) to demonstrate that crossing certain boundaries may at times be salutary, at times neutral, and at times harmful, and 3) to suggest preventive and reparative measures for clinicians dealing with boundary violations in themselves and their patients.

DEFINITIONS

What is a boundary? Is it too amorphous, protean, and abstract to define at all? Should we take refuge by saying, as St. Augustine was supposed to have said about time, "Time? I know what time is, provided you do not ask me"?

Part of the difficulty encountered in defining appropriate boundaries can be related to the historical tradition that modern therapists have inherited. The great figures in the field gave out mixed messages on the issue. Freud, for example, used metaphors involving the opacity of a mirror and the dispassionate objectivity of a surgeon to describe the analyst's role, but his own behavior in the analytic setting did not necessarily reflect the abstinence and anonymity that he advocated in his writings. He sent patients postcards, lent them books, gave them gifts, corrected them when they spoke in a misinformed manner about his family members, provided them with extensive financial support in some cases, and on at least one occasion gave a patient a meal (8). Moreover, the line between professional and personal relationships in Freud's analytic practice was difficult to pinpoint. During vacations he would analyze Ferenczi while walking through the countryside. In one of his letters to Ferenczi, which were often addressed "Dear Son," he indicated that during his holiday he planned to analyze him in two sessions a day but also invited him to share at least one meal with him each day (unpublished manuscript by A. Hoffer). For Freud the analytic relationship could be circumscribed by the time boundaries of the analytic sessions, and other relationships were possible outside the analytic hours. The most striking illustration of this conception of boundaries is Freud's analysis of his own daughter, Anna.

Freud was not alone in establishing ambiguous analytic boundaries. When Melanie Klein was analyzing Clifford Scott, she encouraged him to follow her to the Black Forest for her holiday. Each day during this vacation, Scott underwent analysis for a 2-hour session while reclining on Klein's bed in her hotel room (9). D.W. Winnicott, another therapist of considerable stature, occasionally took young patients into his home as part of his treatment of them (10). In Margaret Little's report of her analysis with Winnicott (11), she recalled how Winnicott held her hands clasped between his through many hours as she lay on the couch in a near-psychotic state. On one occasion he told her about another patient of his who had committed suicide and went into considerable detail about his countertransference reactions to the patient. He also ended each session with coffee and biscuits. These boundary transgressions by highly revered figures have occasionally been cited in ethics hearings as justification for unethical behavior. We wish to stress that these behaviors are no longer acceptable practice regardless of their place in the history of our field.

The problem of the contradiction between what the master therapists wrote and how they actually behaved in the clinical setting was compounded because psychoanalysis and psychotherapy are treatments that occur in a highly private context. The boundaries of the therapeutic relationship and the characteristics of acceptable technique were thus highly subjective and lacked standardization. This lack of clarity was partially addressed by Eissler's classic 1953 paper (12) in which he suggested that in the ideal situation, the analyst's activity should be confined to interpretation. Any deviation from that model technique was defined by Eissler as a parameter. As examples of parameters, he cited Freud's setting a termination date for the Wolf Man and proposed a hypothetical situation in which an analyst might command a phobic patient to expose himself to the feared situation. By this standard of technique, Freud's own behavior, such as offering a meal to the Rat Man, has been regarded as indicative of an earlier technique that Freud subsequently abandoned (13) or a human failing rather than a technical recommendation (14).

Lipton (8) took a strikingly different view of Freud's apparently unorthodox behavior with the Rat Man. He insisted that Freud's providing a meal for the patient should not be considered part of his psychoanalytic technique. Instead, it should be regarded as part of the nontechnical personal relationship that Freud had with this patient. He pointed out that in every analysis, the analyst is called upon to offer assistance in a personal way from time to time. While the ramifications and fantasies produced by such behavior should be thoroughly analyzed, it would be erroneous, in Lipton's view, to expand the concept of technique to include all aspects of the analyst's relationship with the patient. Lipton expressed the following concern: "Modern technique tends to move from the position from which the analyst's technique is judged according to his purpose to one from which the analyst's technique is judged according to his behavior" (8, p. 262). He pointed out that following Eissler's model of analytic technique in its literal terms would cause any noninterpretive comment or action on the part of the analyst to be construed as a parameter.

Another major problem with any attempt to derive definitions of boundaries from psychoanalytic concepts of technique is that technique changes with treatments that are less expressive than analysis. As one moves along the expressive-supportive continuum of psychotherapy (15), one relies less on interpretation and more on alternative interventions such as clarification, confrontation, advice and praise, suggestion, and affirmation. Similarly, partial gratification of transference wishes is associated with supportive psychotherapy, whereas it is generally eschewed in psychoanalysis or highly expressive psychotherapy. Hence, there may be a built-in confusion between the notion of therapeutic boundaries and adjusting the technique to the ego organization of the patient.

Another approach to defining therapeutic boundaries is to conceptualize a therapeutic frame (16, 17), i.e., an envelope or membrane around the therapeutic role that defines the characteristics of the therapeutic relationship. The analyst or therapist constructs the elements of the frame partly consciously and partly unconsciously. These elements include the regular scheduling of appointments, the duration of the appointments, arrangements for payment of the fee, and the office setting itself.

Does the patient's role have a boundary? Spruiell (17) has noted that although the frame is deliberately unbalanced, the patient invariably joins the analyst in elaborating the frame. Most clinicians would agree, basing this answer on recollected violations they have witnessed, such as the patient who refers to the therapist as "Shrinkie" or springs from the chair and tries without warning to sit on the therapist's lap. It is clear, however, that the patient's boundary is a more forgiving and flexible one. The patient cannot be stopped from calling the therapist names, and that is part of the therapeutic process. The patient can be late and that can be discussed, but the therapist should not be late, and so on. In any case our focus here is on the clinician's boundary.

Let us also agree that the role of therapist embraces the structural aspects of therapy in addition to the content; these include time, place, and money, which may, together with other aspects discussed below, represent possible sites for boundary crossings or violations to occur. If this exploration is to be useful, we should adopt the convention that "boundary crossing" in this article is a descriptive term, neither laudatory nor pejorative. An assessor could then determine the impact of a boundary crossing on a case-by-case basis that takes into account the context and situation-specific facts, such as the possible harmfulness of this crossing to this patient. A violation, then, represents a *harmful* crossing, a transgression, of a boundary. An example might be the case of a patient who had experienced severe or traumatic boundary violations in childhood and who might consequently be highly sensitive to later violations, even those usually considered benign. Note also that the difference between a harmful and a nonharmful boundary crossing may lie in whether it is discussed or discussable; clinical exploration of a violation often defuses its potential for harm.

To organize the discussion we consider the matter of boundaries, boundary crossings, and boundary violations under a series of headings: role; time; place and space; money; gifts, services, and related matters; clothing; language; self-disclosure and related matters; and physical contact. Sexual misconduct as an extreme boundary violation has been extensively addressed elsewhere (2, 4, 6, 18) and is not separately reviewed here. We should also point out that in addition to serving as antecedents to sexual misconduct, some of these areas of boundary crossing may represent ethical violations in and of themselves.

ROLE

Role boundaries constitute the essential boundary issue. To conceptualize this entity, one might ask, "Is this what a therapist does?" Although subject to ideological variations, this touchstone question not only identifies the question of clinical role but serves as a useful orienting device for avoiding the pitfalls of role violations.

> A middle-aged borderline patient, attempting to convey how deeply distressed she felt about her situation, leaped from her chair in the therapist's office and threw herself to her knees at the therapist's feet, clasping his hand in both of her own and crying, "Do you understand how awful it's been for me?" The therapist said gently, "You know, this is really interesting, what's happening here—but it isn't therapy; please go back to your chair." The patient did so, and the incident was explored verbally.

Although such limit setting may appear brusque to some clinicians, it may be the only appropriate response to halt boundary-violating "acting in" (especially of the

impulsive or precipitous kind) and to make the behavior available for analysis as part of the therapy.

Almost all patients who enter into a psychotherapeutic process struggle with the unconscious wish to view the therapist as the ideal parent who, unlike the real parents, will gratify all their childhood wishes (19). As a result of the longings stirred up by the basic transference situation of psychotherapy or psychoanalysis, it is imperative that some degree of abstinence be maintained (20). However, strict abstinence is neither desirable nor possible, and total frustration of all the patient's wishes creates a powerful influence on the patient in its own right (8, 19).

In attempting to delineate the appropriate role for the therapist vis-à-vis the patient's wishes and longings to be loved and held, it is useful to differentiate between "libidinal demands," which cannot be gratified without entering into ethical transgressions and damaging enactments, and "growth needs," which prevent growth if not gratified to some extent (21). Greenson (22) made a similar distinction when he noted that the rule of abstinence was constructed to avoid the gratification of a patient's neurotic and infantile wishes, not to lead to a sterile form of treatment in which all the patient's wishes are frustrated.

Efforts to delineate the two varieties of needs often lead to problems in the area of defining the appropriate role for the therapist. Certainly, the patient may have legitimate wishes to be empathically understood, but when the therapist goes too far in the direction of trying to provide parental functions that were not supplied by the original parents, the patient may experience the therapist as making false promises. Casement (21) expressed reservations about Freud's providing a meal to the Rat Man because of the possibility that the patient may have experienced Freud's taking responsibility for a particular part of his life as an implicit promise that Freud was prepared to take over responsibility for other areas of the patient's life as well. Clearly, a therapist cannot become the "good mother" or "good father" in a literal sense and attempt to make up for all the deprivations of childhood. Even when therapists feel as though they are being coerced into a parental role by their patients, they must strive not to conform to the patients' expectations. Spruiell (17) made the following observation: "It is as disastrous for analysts to actually treat their patients like children as it is for analysts to treat their own children as patients" (p. 12).

The therapist's role is subject to some variation, of course. While most therapy is talking, there may be times when it is appropriate, for example, to write a letter on a patient's behalf. Under some circumstances, such a "breach of the frame" (16) might constitute a boundary violation, as when the therapist attempts to intervene in some extratherapeutic realm of the patient's life (e.g., a therapist wrote a stern letter to a patient's employer rebuking the latter for giving the patient excessively burdensome tasks on the job). In addition, since different modalities of therapy are commonly combined, the "talking therapist" might appropriately give medications, conceivably by injection at times—a clear boundary crossing but presumably therapeutic and benign.

TIME

Time is, of course, a boundary, defining the limits of the session itself while providing structure and even containment for many patients, who derive reassurance because they will have to experience the various stresses of reminiscing, reliving, and so forth for a set time only. The beginnings and endings of sessions—starting or stopping late or early—are both susceptible to crossings of this boundary. Such crossings may be subtle or stark.

> A male psychiatrist came in to the hospital to see his female inpatient for marathon sessions at odd times, such as from 2:00 to 6:00 in the morning, rationalizing that this procedure was dictated by scheduling problems. This relationship eventually became overtly sexual.

An interesting prejudice about violating the boundary of time has evolved in sexual misconduct cases, a prejudice deriving from the fact that a clinician interested in having a sexual relationship with a patient might well schedule that patient for the last hour of the day (although, of course, after-work time slots have always been popular). In the fog of uncertainty surrounding sexual misconduct (usually a conflict of credibilities without witnesses), this factor has gleamed with so illusory a brightness that some attorneys seem to presume that because the patient had the last appointment of the day, sexual misconduct occurred! Short of seeing patients straight through the night, this problem does not seem to have a clear solution. Admittedly, however, from a risk-management standpoint, a patient in the midst of an intense erotic transference to the therapist might best be seen, when possible, during high-traffic times when other people (e.g., secretaries, receptionists, and even other patients) are around.

Langs (23) noted that the boundary of time may be psychologically violated when the therapist brings up material from a previous session. Some patients, indeed, feel that this practice is disruptive and is a departure by the therapist from the here and now. However, most clinicians would regard this view as extreme, since effective therapy depends on continuity from session to session.

The issue of the appropriateness of phone calls between psychotherapy sessions is a controversial one, particularly when the patient suffers from borderline personality disorder. Some therapists view such phone calls as necessary and expectable in light of the borderline patient's difficulties with evocative memory (24, 25). In other words, the patient's inability to evoke a holding, soothing introject causes anxiety of catastrophic proportions related to the fear that the therapist has disappeared. Phone calls are a way of reestablishing contact with the therapist and soothing this anxiety, which might otherwise lead to ill-advised self-

destructive behavior. On the other hand, other therapists view such calls as unnecessary and countertherapeutic (26, 27). These therapists go to great lengths in the initial contractual period, at the beginning of therapy, to extract an agreement from the patient that phone calls will be used only in emergency situations. This controversy reflects how a boundary violation may be defined according to the extent to which the appropriate treatment is viewed as having an expressive versus a supportive emphasis.

PLACE AND SPACE

The therapist's office or a room on a hospital unit is obviously the locale for almost all therapy; some exceptions are noted in the next section. Exceptions usually constitute boundary crossings but are not always harmful. Some examples include accompanying a patient to court for a hearing, visiting a patient at home, and seeing a patient in the intensive care unit after an overdose or in jail after an arrest.

Some boundary crossings of place can have a constructive effect. As with medication, the timing and dosage are critical.

> After initially agreeing to attend his analysand's wedding, the analyst later declined, reasoning that his presence would be inappropriately distracting. Later, after the death of the analysand's first child, he attended the funeral service. Both his absence at the first occasion and his presence at the second were felt as helpful and supportive by the analysand. They both agreed later that the initial plan to attend the wedding was an error.

A relevant lesson from this example is that boundary violations can be reversed or undone with further consideration and discussion. At times, an apology by the therapist is appropriate and even necessary.

Some sexual misconduct cases reveal space violations that seem to manifest wishes for fusion on the part of the therapist, as in the following case.

> A lesbian therapist treating a female patient would contrive to use the bathroom at the clinic whenever the patient did so and, entering the adjoining stall, would attempt to continue the conversation. The relationship became overtly and exploitatively sexual, with the therapist often wearing the patient's clothes to work the next day after they had spent the night together.

Sorties out of the office usually merit special scrutiny. While home visits were a central component of the community psychiatry movement, the shift in the professional climate is such that the modern clinician is best advised to perform this valuable service with an opposite-sex chaperon and to document the event in some detail.

Sessions during lunch are an extremely common form of boundary violation. This event appears to be a common way station along the path of increasing boundary crossings culminating in sexual misconduct. Although clinicians often advance the claim that therapy is going on, so, inevitably, is much purely social behavior; it does not *look* like therapy, at least to a jury. Lunch sessions are not uncommonly followed by sessions during dinner, then just dinners, then other dating behavior, eventually including intercourse.

Sessions in cars represent another violation of place. Typically, the clinician gives the patient a ride home under various circumstances. Clinician and patient then park (e.g., in front of the patient's house) and finish up the presumably therapeutic conversation. From a fact finder's viewpoint, many exciting things happen in cars, but therapy is usually not one of them.

The complexity of the matter increases, however, when we consider other therapeutic ideologies. For example, it would not be a boundary violation for a behaviorist, under certain circumstances, to accompany a patient in a car, to an elevator, to an airplane, or even to a public restroom (in the treatment of paruresis, the fear of urinating in a public restroom) as part of the treatment plan for a particular phobia. The existence of a body of professional literature, a clinical rationale, and risk-benefit documentation will be useful in protecting the clinician in such a situation from misconstruction of the therapeutic efforts.

MONEY

Money is a boundary in the sense of defining the business nature of the therapeutic relationship. This is not love, it's work. Indeed, some would argue that the fee received by the therapist is the only appropriate and allowable material gratification to be derived from clinical work (28). Patient and clinician may each have conflicts about this distinction (29), but consultative experience makes clear that trouble begins precisely when the therapist stops thinking of therapy as work.

On the other hand, most clinicians learned their trade by working with indigent patients and feel that some attempt should be made to pay back this debt by seeing some patients for free—a form of "tithing," if you will. Note that this *decision*—to see a patient for free and to discuss that with the patient—is quite different from simply letting the billing lapse or allowing the debt to mount. The latter examples are boundary crossings, perhaps violations.

Consultative experience also suggests that the usual problem underlying a patient's mounting debt is the clinician's conflict about money and its dynamic meanings. Initially reluctant to bring up the unpaid bill, the clinician may soon become too angry to discuss it. Explorations of the dynamic meaning of the bill are more convincing when they do not take place through clenched teeth. A clinician stuck at this countertransference point may simply let it slide. In the minds of fact finders, this raises a question: "The clinician seems curiously indifferent to making a living; could the patient be paying in some other currency?"—a line of speculation one does not wish to foster.

In rural areas even today, payments to physicians may take the form of barter: when the doctor delivers your child, you pay with two chickens and the new calf. For the dynamic therapist this practice poses some problems, because it blurs the boundary between payment and gift (covered in the next section). The clinician should take a case at a reasonable fee or make a *decision* to see the patient for a low fee (e.g., one dollar) or none. Barter is confusing and probably ill-advised today. Of course, all such decisions require documentation.

GIFTS, SERVICES, AND RELATED MATTERS

> A client became very upset during an interview with her therapist and began to cry. The therapist, proffering a tissue, held out a hand-tooled Florentine leather case in which a pocket pack of tissues had been placed. After the patient had withdrawn a tissue, the therapist impulsively said, "Why don't you keep the case?" In subsequent supervision the therapist came to understand that this "gift" to the patient was an unconscious bribe designed to avert the anger that the therapist sensed just below the surface of the patient's sorrow.

This gift was also a boundary violation, placing unidentified obligations on the patient and constituting a form of impulsive acting in. A related boundary violation is the use of favors or services from the patient for the benefit of the therapist, as Simon's startling vignette illustrates:

> Within a few months of starting . . . psychotherapy, the patient was returning the therapist's library books for him "as a favor." . . . The patient began having trouble paying her treatment bill, so she agreed—at the therapist's suggestion—to clean the therapist's office once a week in partial payment . . . . The patient also agreed to get the therapist's lunch at a nearby delicatessen before each session. (6, p. 106)

The obvious exploitive nature of these boundary violations destroys even the semblance of therapy for the patient's benefit.

When Freud heard that one of his patients was planning to buy a set of his complete works, he gave the patient the set as a gift (30). Immediately following the receipt of this gift, Freud's patient found that he was unable to use his dreams productively in the analysis as he had before. Freud related this "drying up" to the gift and noted, "You will see from this what difficulties gifts in analysis always make" (p. 42).

Other boundary crossings can be relatively minor but can promote a chain of subsequent crossings, as in this example:

> A patient walked into the room while her therapist was pouring coffee from a carafe. He later described how he had felt socially incapable of not offering some coffee to the patient and had indeed offered some. At the next session, the patient brought doughnuts.

As the vignette shows, many boundary problems may arise at the interface between manners and technique.

In contrast to the potentially harmful or at least confusing effects of the preceding examples, compare the practice (not uncommon among psychopharmacologists) of giving patients, as part of treatment, educational texts designed for laypersons (e.g., giving *Moodswing* [31] to a patient with bipolar disorder). Such a boundary crossing may foster mastery of the illness through information—a positive result. A similar point might be made for judicious "gifts" of medication samples for indigent patients. These two instances represent clear boundary crossings that have some justification. Ideally, even these should be discussed with an ear to any possible negative effects.

> A patient in long-term therapy had struggled for years with apparent infertility and eventually, with great difficulty, arranged for adoption of a child. Two years later she unexpectedly conceived and finally gave birth. Her therapist, appreciating the power and meaning of this event, sent congratulatory flowers to the hospital.

In this case, the therapist followed social convention in a way that—though technically a boundary crossing—represented a response appropriate to the real relationship. Offering a tissue to a crying patient and expressing condolences to a bereaved one are similar examples of appropriate responses outside the classic boundaries of the therapeutic relationship.

CLOTHING

Clothing represents a social boundary the transgression of which is usually inappropriate to the therapeutic situation, yet a patient may appropriately be asked to roll up a sleeve to permit measurement of blood pressure. Excessively revealing or frankly seductive clothing worn by the therapist may represent a boundary violation with potentially harmful effects to patients, but the issue can also be overdone, as in the following case.

> A patient in a western state, as part of a sexual misconduct allegation that a jury later found to be false, accused the therapist (among other things) of conducting therapy sessions with the top two buttons of his shirt undone. While such a phenomenon might conceivably represent a violation for a very sensitive patient, evidence was introduced that revealed the exaggerated nature of this claim in *this* case.

Berne (32) noted the technical error of the male clinician who, confronting a patient whose skirt was pulled up high, began to explain to the patient his sexual fantasies in response to this event. Berne suggested instead saying to the patient, "Pull your skirt down." Similar directness of limit setting appears to be suited to the patient who—either from psychosis or the wish to provoke—begins to take off her clothes in the office. As before, the comment, "This behavior is inappropriate,

and it isn't therapy; please put your clothes back on," said in a calm voice, is a reasonable response.

LANGUAGE

As part of the otherwise laudable efforts to humanize and demystify psychiatry a few decades back, the use of a patient's first name was very much in vogue. While this may indeed convey greater warmth and closeness, such usage is a two-edged sword. There is always the possibility that patients may experience the use of first names as misrepresenting the professional relationship as a social friendship (28). There may well be instances when using first names is appropriate, but therapists must carefully consider whether they are creating a false sense of intimacy that may subsequently backfire.

> A middle-aged woman tried for more than a year to get her therapist to use her first name, but the requests were denied, and exploration of the issue took place instead. After some time the patient recovered memories of previously repressed material, in part because of increased trust in the therapist. The patient spontaneously related her trust to the use of last names as a boundary issue; boundaries had been badly blurred in her family and this had included sexual abuse.

There are distinct advantages to addressing the adult in the patient, in terms of fostering the adult observing ego for the alliance. Trainees often do not see the paradox of expecting adult behavior on the ward from someone they themselves call "Jimmy," which is what people called the patient when he was much younger. Last names also emphasize that this process is work or business, an atmosphere which may promote a valuable mature perspective and minimize acting out. In addition, calling someone by the name used by primary objects may foster transference perceptions of the therapist when they are not desirable, as with a borderline patient prone to forming severe psychotic transferences. For balance, however, recall that use of last names may also sound excessively distant, formal, and aloof.

Tone is also a part of language. A patient won a settlement in an allegation of sexual misconduct when the tape recording she had made of a phone call from her therapist revealed his intimate, seductive tone. The therapist's attorney urged the settlement for fear that the jury would hear the intimate tone as evidence of a sexual relationship.

Word choice can also be violative, as when the therapist inquires, "What are you feeling now in your vagina?" Note that this inquiry might be proper in analytic therapy after appropriate preparation. Clinical utility aside, the way in which such explorations may violate boundaries should be kept in mind.

Finally, psychotherapy may be a forum for sadomasochistic enactments in which aggressive verbal abuse grows out of countertransference sadism. Cruel and contemptuous comments by the therapist may be rationalized as therapeutic confrontation.

SELF-DISCLOSURE AND RELATED MATTERS

Few clinicians would argue that the therapist's self-disclosure is always a boundary crossing. Psychoanalysis and intensive psychotherapy involve intense personal relationships. A useful therapeutic alliance may be forged by the therapist's willingness to acknowledge that a painful experience of the patient is familiar to himself (19). However, when a therapist begins to indulge in even mild forms of self-disclosure, it is an indication for careful self-scrutiny regarding the motivations for departure from the usual therapeutic stance. Gorkin (33) observed that many therapists harbor a wish to be known by their patients as a "real person," especially as the termination of the therapy approaches. While it may be technically correct for a therapist to become more spontaneous at the end of the therapeutic process, therapists who become more self-disclosing as the therapy ends must be sure that their reasons for doing so are not related to their own unfulfilled needs in their private lives but, rather, are based on an objective assessment that increased focus on the real relationship is useful for the patient in the termination process.

Self-disclosure, however, represents a complex issue. Clearly, therapists may occasionally use a neutral example from their own lives to illustrate a point. Sharing the impact of a borderline patient's behavior on the therapist may also be useful. The therapist's self-revelation, however, of personal fantasies or dreams; of social, sexual, or financial details; of specific vacation plans; or of expected births or deaths in the family is usually burdening the patient with information, whereas it is the patient's fantasies that might best be explored. The issue is somewhat controversial: a number of patients (and, surprisingly, some therapists) believe that the patient is somehow entitled to this kind of information. In any case, it is a boundary violation and as such may be used by the legal system to advance or support a claim of sexual misconduct. The reasoning is that the patient knows so much about the therapist's personal life that they must have been intimate (compare the remark by a board of registration, quoted earlier).

Subtler variations on the information theme may occur, as when a therapist sees members of a couple in parallel treatment but separately alludes in one member's session to material from the other's. Sensitivity in this area may run quite high.

> A patient had a dream involving Nazis. In the interpretation the therapist suggested that this detail referred to himself. The patient seemed doubtful. The therapist noted that the interpretation was based in part on the fact that other patients of his had dreamed of Nazis in response to the therapist's German last name. The patient's mood changed; only later was she able to tell the therapist how violated she had felt at his "intruding" other patients into the session.

Although the intrusion was at a verbal level only, the impact was clear for this patient, who had been sub-

jected to some disregard of her boundaries in previous therapy.

Finally, the boundary can be violated from the other side. An example would be the therapist's using data from the therapy session for personal gain, such as insider information on stock trading, huge profits to be made in real estate, and the like.

PHYSICAL CONTACT

To place the issue of physical contact in context, it should be noted that psychiatrists traditionally performed their own physical examinations. This practice has declined so markedly that a senior psychiatrist recently wrote about examining a patient's bruised leg as a major return to the past. Hospitals commonly use internists for this purpose. Psychiatric residents still do their own physical examinations but commonly maintain distance by examining each other's patients. Abnormal Involuntary Movement Scale examinations for tardive dyskinesia are often the only routine physical contact.

There is room here for regrets. Physicians working with a patient with AIDS or HIV seropositivity often describe wishing to touch the patient in some benign manner (pat the back, squeeze an arm, pat a hand) in every session. They reason that such patients feel like lepers, and therapeutic touch is called for in these cases. But even such humane interventions must be scrutinized and, indeed, be documented to prevent their misconstruction in today's climate.

From the viewpoint of current risk-management principles, a handshake is about the limit of social physical contact at this time. Of course, a patient who attempts a hug in the last session after 7 years of intense, intensive, and successful therapy should probably not be hurled across the room. However, most hugs from patients should be discouraged in tactful, gentle ways by words, body language, positioning, and so forth. Patients who deliberately or provocatively throw their arms around the therapist despite repeated efforts at discouragement should be stopped. An appropriate response is to step back, catch both wrists in your hands, cross the patient's wrists in front of you, so that the crossed arms form a barrier between bodies, and say firmly, "Therapy is a talking relationship; please sit down so we can discuss your not doing this any more." If the work degenerates into grabbing, consider seriously termination and referral, perhaps to a therapist of a different gender.

What is one to make of the brands of therapy that include physical contact, such as Rolfing? Presumably, the boundary extends to that limited physical contact, and the patient expects it and grants consent; thus, no actual violation occurs. Massage therapists may struggle with similar issues, however. In other ideologies the issue may again be the impact of the appearance of a violation:

> A therapist—who claimed that her school of practice involved hugging her female patient at the beginning and end of every session, without apparent harm—eventually had to terminate therapy with the patient for noncompliance with the therapeutic plan. The enraged patient filed a sexual misconduct claim against the therapist. Despite the evidence showing that this claim was probably false (a specious suit triggered by rage at the therapist), the insurer settled because of the likelihood that a jury would not accept the principle of "hug at the start and hug at the end but no hugs in between." If the claim was indeed false, this is a settlement based on boundary violations alone.

At another level this vignette nicely suggests how nonsexual boundary violations may be harmful to a patient in much the same way that actual sexual misconduct is. Instead of engaging the patient in a mourning process to deal with the resentment and grief about the deprivations of her childhood, the therapist who hugs a patient is often attempting to provide the physical contact normally offered by a parent. The patient then feels entitled to more demonstrations of caring and assumes that if gratification in the form of hugs is available, other wishes will be granted as well (compare Smith's concept of the "golden fantasy" that all needs will be met by therapy [34]). When actual physical contact occurs, the crucial psychotherapeutic distinction between the symbolic and the concrete is lost (21), and the patient may feel that powerful infantile longings within will finally be satisfied.

CONCLUSIONS

Boundary crossings may be benign or harmful, may take many forms, and may pose problems related to both treatment and potential liability. The differences in impact may depend on whether clinical judgment has been used to make the decision, whether adequate discussion and exploration have taken place, and whether documentation adequately records the details. The complexity of the subject and the variability of results from case-by-case analysis merit empirical study. Educational materials are available through the Office of Public Affairs of the American Psychiatric Association. Heightened awareness of the concepts of boundaries, boundary crossings, and boundary violations will both improve patient care and contribute to effective risk management.

In an effort to prevent more serious boundary violations of a sexual nature, Epstein and Simon (28) have developed an exploitation index which comprises a list of questions that therapists can ask themselves about their current behavior with patients. In this manner these authors have attempted to provide an ongoing self-monitoring system. While such approaches may be useful for some clinicians, we must acknowledge that considerable personal variation exists in our field. The relationships between therapist and patient vary from one therapist to another, and there are even variations across patients in the practice of one therapist. As Lipton (8) observed, it is ultimately impossible to codify or prescribe a personal relationship between therapist and

patient in a precise manner. Perhaps the best risk management involves careful consideration of any departures from one's usual practice accompanied by careful documentation of the reasons for the departure. Finally, the value of consultation with a respected colleague should be a built-in part of every practitioner's risk-management program.

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Chapter 1
The Clinician's Dilemma: Under-Treated Pain Versus Prescription Drug Misuse

In recent years, two compelling public health trends have become entwined like the twin serpents in the caduceus: first came increased clinical attention across all medical specialties to the under-treatment of pain, generating increased prescribing of opioid analgesics. This was followed by a shift in patterns of drug misuse from illicit to prescription drugs—most notably a dramatic rise in diversion and non-medical use of opioid pain medications within the United States.

As the gatekeepers of prescription medications, clinicians are being enlisted to fight on two fronts: combating pain, while simultaneously defending against the misuse of and addiction to opioid pain medications. Some clinicians bristle at adding "pharmacovigilance" and "risk management" to their already lengthy task list. But the combination of potential therapeutic benefit and high risk associated with opioid analgesics leaves us no alternative but to become more committed and sophisticated risk managers.

The practice of medicine is often a balancing act. Nowhere is this truer than in the treatment of patients in pain. Pain is the most common reason patients seek care, and treating pain often presents clinicians with significant challenges —not least of which is the fact that pain is always subjective. None of us can prove that someone does or does not have pain. It is always an "untestable hypothesis."

Opioids are potent and reliable pain relievers, but they are not a panacea. Opioids do not work for all pain, or for all patients, and they may cause adverse effects ranging from mild to life threatening. The primary clinical goal is to balance the legitimate need to treat the harm that comes with ongoing pain with the equally compelling need to minimize other risks of harm, to both the patient and society at large.

Over the past two decades, clinicians who treat patients in pain have been buffeted by the winds of both data and opinion, alternately pushing

pain management towards and away from opioid therapy. Prior to the 1990s, clinicians often viewed opioid pain medications with skepticism and avoided prescribing them, even when risks were thought to be low. This perspective gave way to the recognition that many patients were being under-treated for their pain, leading to increased interest in the clinical value of opioids and a dramatic rise in rates of opioid prescribing for pain. In her 2008 testimony to the U.S. Senate Committee on Judiciary, National Institute for Drug Abuse (NIDA) Director Nora D. Volkow, M.D., stated: *"Prescriptions for opiates have escalated from around 40 million in 1991 to nearly 180 million in 2007, with the U.S. their biggest consumer. The U.S. has supplied 99 percent of the world total for hydrocodone (e.g., Vicodin) and 71 percent of oxycodone (e.g., OxyContin)."*[3] Today, opioids are the most-prescribed class of prescription medications in the United States, with hydrocodone as the single most prescribed drug in the US. Factors contributing to the rise in opioid prescribing include the introduction of long-acting formulations and novel delivery systems, as well as prescriber concerns over the dangers of non-opioid analgesics such as non-steroidal anti-inflammatory drugs (NSAIDS).

Escalating opioid prescribing rates coincided with a dramatic rise in diversion and nonmedical use of these powerful drugs, perhaps due in part to the misconception by abusers that prescription medications are less dangerous than illicit drugs. Another potential contributory factor was the proliferation of hundreds of rogue Internet sites where consumers could purchase opioid medications without prescriptions, or via "online consultations" with real or bogus physicians. Meanwhile, "pill mills" where opioids are prescribed indiscriminately to anyone who would pay, proliferated in states such as Florida and Kentucky. Alarming spikes in addiction and unintended overdose deaths paralleled heightened prescribing rates of opioid medications.

It remains unclear exactly how much of this problem of misuse, addiction, and unintended overdose death is related to well-intended, but possibly under-informed or under-educated prescribers who over-prescribe opioids for legitimate patients in pain.

The winds of clinical, regulatory, and public opinion are now pushing clinicians toward a more cautious approach to opioid prescribing with a greater emphasis on risk management. This paradigm shift is being driven by undeniably dire statistics that reveal the scope of devastation caused by inappropriate use of opioid medications.

Clinicians, however, still face the challenge of balancing the real need for pain control with the need to minimize and manage the risks associated with opioid analgesics. My view is that this balancing act is not so different from the decisions required when clinicians use many other potentially risky pharmacological therapies. Solid medical practice is founded upon making rational and individualized decisions based on risk-benefit analyses, and I believe we can make these medical decisions about controlled substances in a manner that best serves the interests of our patients and society at large. In the early days of general anesthesia use, anesthesia-related morbidity and mortality occurred at unacceptable rates. Many thought anesthesia was too dangerous because clinicians had not yet learned how to use this tool safely. Many indispensible drugs have high risks. But over time, the medical community has established safe parameters for their use in appropriate cases.

Employing effective risk management is simply good medicine. Clinicians routinely use dangerous treatments—such as NSAIDS, carbamazepine, chemotherapy, and even insulin, to cite just a few examples—and we do so only when the potential benefits outweigh the risks. We use great care to deliver these risky therapies safely. The challenge posed by opioid analgesics is that not only are they potentially dangerous for patients, they are highly sought-after for misuse.

Prescribing opioid analgesics responsibly should not require that clinicians stake out polarized positions on the issues. Opioids are neither inherently "good" nor inherently "bad." Nor is there any need to be "pro" or "con" when it comes to opioids. All clinicians can agree that we must support the use of opioids in those cases where it is in the patient's best interest and oppose it when it is not. Your medical judgment, founded on prudent and shared medical decision-making, must weigh the potential risks and benefits of opioid therapy against alternative treatment options. The risk of non-treatment must also be included in this risk-benefit analysis. In daily practice, that means a prescriber may be "pro" opioid for one patient and "con" for another. This book provides a practical foundation for clinicians to perform the balancing act required in opioid management for persistent pain.

Prescription Drug Misuse

The chapters to come will describe how clinicians can implement responsible opioid prescribing in their busy daily practices. But first,

I want to be sure you fully appreciate the magnitude of the current problems with prescription drug misuse. Let's be clear: the misuse of prescription opioid drugs in the United States has created a significant and growing public health crisis of addiction, overdose, and death. The opioid medications associated with these problems include immediate and extended release products, as well as methadone. Many people directly affected by the crisis have been previously healthy and have had no history of substance misuse.[4]

If nothing you've read or heard so far has focused your mind on this public health crisis, the following statistics should:

- Between 1998 and 2008, the rate of opioid misuse increased 400%.[5]
- More than 6 million Americans are abusing prescription drugs—more than the number abusing cocaine, heroin, hallucinogens, and inhalants, combined.[6]
- Emergency-room visits related to pharmaceutical opioids doubled between 2004 and 2008.[7]
- Between 1998 and 2008, there was a fivefold increase in drug treatment admissions for prescription opioids.[8]
- The number of deaths nationwide attributable to prescription opioid analgesics quadrupled between 1999 and 2007.[7]
- From 1999 to 2005 the number of hospital records related to poisoning deaths mentioning methadone increased 468%.[9]
- Opioid overdose is now the second-leading cause of accidental death in America, exceeded only by car crashes; in 17 states opioid overdose is the leading cause of accidental death.[10]

Behind these figures lie millions of tragic stories of untimely death, fractured families, shattered dreams, and wasted lives. The same spectrum of ills can be found in the wake of any abused drug, including alcohol, tobacco, heroin, and cocaine, to name just a few. But the fact that opioids are *prescription* drugs makes it imperative that prescribers become more vigilant risk managers as they care for patients in pain.

The Continuing Need for Pain Management

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care.

As we work to reduce diversion and misuse of prescription opioids, it's critical to remember that the problem of unrelieved pain remains as urgent as ever.

Medicine and public health measures have succeeded in greatly increasing longevity. But although we live longer as a population, we do not necessarily live better. A 2011 congressionally mandated study by the Institute of Medicine Committee on Advancing Pain Research, Care, and Education reported that *116 million Americans suffer from chronic pain*, costing up to $635 billion annually in treatment and lost productivity.[11]

Other surveys set the problem of chronic pain in stark relief:

- Among all adults 65 years of age and over who reported pain lasting more than 24 hours, 60% stated that it lasted more than one year.[11]
- In 2004, more than 25% of adults 18 years of age and over reported low back pain in the past 3 months, with high rates of limited activity and serious psychological distress.[12]
- Low back pain is the second most common neurological ailment in the US behind headache (when every type and severity level of headache are lumped together).[13]
- The incidence of pain in the US is greater than that of diabetes, heart disease and cancer *combined*.[13, 14]
- Tragically, research shows that 50-70% of patients die in moderate to severe pain, despite the availability of opioids and other therapies to control pain.[15]

Without doubt, there *have* been improvements in pain treatment in recent years. Significant efforts have begun to reduce the incidence of untreated or under-treated pain in children, older patients, and in all other vulnerable patient populations. The following general principles are now widely accepted for pain management, according to current clinical guidelines, policy statements, and organizational goals:[16]

- Pain management is integral to good medical practice for all patients.
- Opioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins.
- Patients should not be denied opioid medications except when the risks outweigh the potential benefits.

- The use of opioids for other than legitimate medical purposes poses a threat to the individual and society.
- Prescribers have a responsibility to minimize the potential for the misuse and diversion of controlled substances.

Although pain remains the most common reason a patient seeks medical attention, most clinicians are grossly under-trained in pain assessment, pain management, and appropriate use of controlled substances. Four factors contribute to the ongoing problem of both under-treated pain and opioid over-prescribing:

1. Lack of knowledge among prescribers about current pain management guidelines, risk management practices, and research in pain medicine.
2. Lack of knowledge among prescribers about addiction, dependence, and misuse.
3. The perception that prescribing adequate amounts of opioids (high or low dosages) will result in unnecessary scrutiny by regulatory authorities.
4. Lack of understanding of regulatory policies and processes

To these factors might be added a fifth: the absence of a clearly stated overview of how government regulations and professional guidelines for prescribing can be incorporated into the hectic daily practice of clinicians. This book answers this critical need.

Responsible Prescribing With Incomplete Data

Although both the problem of prescription drug misuse and the need for adequate pain relief are evident, clear clinical data to guide practitioners in balanced and responsible opioid prescribing remain elusive. But the absence of complete information about the risks and benefits of opioids does not relieve practitioners of the obligation to treat patients as safely and effectively as possible. Practicing medicine with incomplete and sometimes conflicting data is familiar territory for primary care and specialist clinicians alike, whether treating cardiac disease, cancer, or chronic pain. We remain obliged to treat pain as best we can, given the state of research, and to become and remain as well-informed as possible about the risks and benefits of specific medications. That's what this book is all about.

Many difficult issues regarding the use of opioids remain poorly supported, one way or the other, by clear science. In the chapters to come, I'll deal with many of the challenges presented by vexing questions that have limited science in guiding clinical practice, such as the efficacy of opioids in chronic pain, rates of and concerns about addiction and misuse, and dose escalation and discontinuation.

The evidence supporting long-term efficacy for opioid use in chronic noncancer pain is limited and of low quality. The 2009 APS-AAPM Clinical Guidelines For the Use of Chronic Opioid Therapy in Chronic Noncancer Pain concluded that clinical data on efficacy are currently not adequate to support or refute the role this treatment should play for any given individual (Appendix B). In addition, the rate of addiction or misuse in patients given opioids for chronic pain is commonly questioned. It was previously believed that addiction associated with opioids for chronic pain was rare. The data upon which these conclusions were drawn, however, have been found to be inadequate and seriously flawed. Although we currently do not know the exact rate of addiction in patients legitimately prescribed opioids for pain or the rate of overall misuse, we know that rates are high enough that they should be considered a significant potential adverse effect.

Addiction and misuse are often a major concern associated with opioid use. Opioids, however, have a wide range of potential adverse effects that can predispose a patient to serious morbidity and mortality. Much of this risk relates to respiratory depression, potentially leading to unintended overdose, negative impact on endocrine function, and possibly, heightened fracture risk related to effects on bone metabolism and from falls. Risk is increased among the elderly; those with impaired renal or hepatic function; individuals with cardiopulmonary disorders, such as chronic obstructive pulmonary disease (COPD); congestive heart failure (CHF), sleep apnea, or mental illness; and in patients who combine opioids with other respiratory depressants such as alcohol, sedative-hypnotics, benzodiazepines, or barbiturates.

In cases where patients do not respond to long-term opioid therapy, some clinicians routinely escalate the dose, hoping that higher doses will either achieve the desired analgesia or overcome pharmacological tolerance. Many clinicians were taught that there was no ceiling dose with opioids, and to titrate up until pain was relieved (or there were intolerable side effects). Escalating dosages as a reflexive response to poor

efficacy, however, is a serious mistake. Patients who do not respond to a trial of opioids, with structured dose titration and monitoring, must be evaluated to determine whether or not the pain is responsive to opioids, whether efficacy is limited because of side effects or inadequate dosing, or whether misuse or diversion is possible. Scientific data are inadequate to guide us in one direction or another but common sense can help to a great extent. We know that dose escalation comes with increased risk, so when increased dosing is thought to be warranted, we must proportionately raise our vigilance, with a clear view toward indicators of efficacy in the absence of indicators of adverse effects or aberrant use. Prescribers must develop distinct, measurable end-points for their treatment plans (e.g., functional capacities, exercise tolerance, sleep, mood, social interaction), and they must be as willing to *discontinue* therapy as they are to initiate it. A structured approach to discontinuing opioid therapy (commonly referred to as an "exit strategy") should be part of treatment planning at dose initiation.

Starting opioid therapy can be easier than stopping it. But, if you are not prepared to stop the treatment—if it does not work, if the chronic pain syndrome subsides, or if its risk outweighs its benefits—you probably should not start it. Discontinuing a long-term opioid regime is easiest at the earliest signs of ineffectiveness, intolerance, or aberrant use. Assessment of efficacy and safety should occur before dosages rise to high levels, as high dosages require clear evidence of benefit without adverse outcomes or aberrant patient behavior. Long-term opioid therapy that continues without clear evidence of benefit, or despite evidence of adversity or aberrant use, may contribute to an iatrogenic problem where tapering becomes more difficult, or requires protracted periods of time or specialized intervention.

In an effort to guide healthcare providers in the context of unanswered research questions, the Centers for Disease Control and Prevention (CDC) in 2010 issued the following recommendations, which it acknowledged are based on promising interventions and expert opinion, not rigorous evidence-based research:[10]

- Use opioid medications for acute or chronic pain only after determining that alternative therapies do not deliver adequate pain relief. The lowest effective dose of opioids should be used.
- In addition to behavioral screening and use of patient contracts, consider random, periodic, urine testing for opioids and other drugs

for any patient less than 65 years old with noncancer pain who is being treated with opioids for more than six weeks.
- If a patient's dosage has increased to ≥120 morphine milligram equivalents per day without substantial improvement in pain and function, seek a consult from a pain specialist.
- Do not prescribe long-acting or controlled-release opioids (e.g., OxyContin®, fentanyl patches, and methadone) for acute pain.
- Periodically request a report from your state prescription drug monitoring program on the prescribing of opioids to your patients by other providers.

All of these points will be explored in more depth in later chapters. For now, let me briefly summarize the fundamental tenets of responsible opioid prescribing, as presented in this book, which expand upon the CDC recommendations:

Summary

PATIENT EVALUATION AND SELECTION

- Reserve long-term opioid therapy for patients who have tried other potentially effective treatments that pose less risk, including physical therapy, exercise, cognitive-behavioral therapy, and non-opioid analgesics.
- Screen patients before and during treatment for risks of all adverse outcomes, including those with mental illness and substance misuse, cardiopulmonary disease, and endocrine disorders.
- Understand that patients may be reluctant to disclose a history of substance misuse. Always check the medical record, a prescription drug-monitoring database, and third parties within the allowable circle of care.
- Don't start long-term use of opioids by default. Long-term opioid prescribing should generally be reserved for persistent or chronic pain and should only occur after careful patient selection, discussion of risks, and the setting of realistic expectations and functional goals.
- Educate patients about the risks and benefits of opioid medications, as well as about their proper storage and disposal, so that they can make informed decisions about choosing or rejecting opioid therapy.

TREATMENT PLANS

- Be sure that the decision to start treatment is clearly agreed to by the patient and prescriber, and that each is informed about (and is willing to work toward) treatment continuation or termination based on functional goals and safety.
- Explain to patients that opioids used to treat acute pain are for time-limited use. At the outset, set expectations that opioids should be discontinued when the pain problem is no longer acute.
- Avoid dispensing more medication than necessary. A 30-day supply for acute pain may be more than necessary. In treating acute pain with opioids, give only the amount believed to be needed. Be aware that excess medication may serve to stock an uncontrolled medicine cabinet and increase the risks of accidental toxicity or diversion.

PERIODIC REVIEW AND MONITORING

- Never continue long-term opioid therapy with patients who, after reasonable efforts, show inadequate progress toward functional goals.
- Consult with more specialized healthcare providers if a patient's problems exceed your range of expertise. Do not accept unmanageable risk just because the appropriate consultant may not be available.
- Don't abandon patients with aberrant behaviors or a prescription drug problem. Consider all possible causes for the behavior and remain open to employing other potentially safe treatments.
- Question how your patient is using his or her opioids. Some patients may not use the drugs you prescribe as directed. They may vary the dosing or combine them with other dangerous substances, drugs, or alcohol in ways that are not advisable.
- Have clear treatment parameters beyond which continued use requires re-evaluation. For instance, acute pain that continues to require opioid therapy should be fully re-evaluated.
- Exercise compassion and trust—but verify. Recognize that misuse and addiction often coincide with denial and a striking lack of insight. Clinicians, therefore, must use all available tools to discern these problems as early as possible. This includes closely monitoring functional and behavioral status, utilizing urine toxicity screens and prescription drug monitoring systems, and remaining engaged in care before and after any potential adverse outcomes.

In the rest of this book I will "unpack" these bullet points with an eye to the real-world, day-to-day demands made on clinicians like you and me. Although the challenges of balancing the potential benefits and risks of opioids are real, they're no different than the choices presented by potentially risky treatments in other spheres of medical practice. As you will see, responsible opioid prescribing often relies on subtle changes of attitude, relatively simple changes to policies or procedures, and a willingness to examine one's current approach to opioids. When opioids are prescribed responsibly, both patients and clinicians benefit.

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Review Articles

Core Competencies for Pain Management: Results of an Interprofessional Consensus Summit

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Abstract

Objective. The objective of this project was to develop core competencies in pain assessment and management for prelicensure health professional education. Such core pain competencies common to all prelicensure health professionals have not been previously reported.

Methods. An interprofessional executive committee led a consensus-building process to develop the core competencies. An in-depth literature review was conducted followed by engagement of an interprofessional Competency Advisory Committee to critique competencies through an iterative process. A 2-day summit was held so that consensus could be reached.

Results. The consensus-derived competencies were categorized within four domains: multidimensional nature of pain, pain assessment and measurement, management of pain, and context of pain management. These domains address the fundamental concepts and complexity of pain; how pain is observed and assessed; collaborative approaches to treatment options; and application of competencies across the life span in the context of various settings, populations, and care team models. A set of values and guiding principles are embedded within each domain.

Conclusions. These competencies can serve as a foundation for developing, defining, and revising curricula and as a resource for the creation of learning activities across health professions designed to advance care that effectively responds to pain.

Key Words. Pain; Pain Management; Clinical Competence; Competencies; Interprofessional; Curriculum; Education; Health Professions

Introduction

Pain is the most common reason individuals visit a health care professional. Worldwide, inadequately managed pain is the source of major human and economic costs for patients, their families, and society [1]. According to the Institute of Medicine (IOM), approximately 100 million Americans suffer from chronic pain at an estimated annual cost of approximately 600 billion dollars [2]. This figure exceeds the cost of each of the nation's priority health conditions [3]. These estimates do not include the considerable burdens of acute pain and cancer-related pain [1]. Despite its importance in clinical practice, pain management receives little emphasis in the curricula of most prelicensure health care professional education programs [4–13]. In its 2011 monograph on pain in America, the IOM noted, *"Curricula for all health professions are full, and advocates of many important causes compete for a greater share of students' and clinicians' valuable educational time. Yet despite the large role that care of patients with pain will play in their daily practice, many health professionals, especially physicians, appear*

underprepared for and uncomfortable with carrying out this aspect of their work. These professionals need and deserve greater knowledge and skills so they can contribute to the necessary cultural transformation in the perception and treatment of people with pain." [2]

Historically, the value of core curricula for pain education was recognized in the 1990s by the International Association for the Study of Pain (IASP); Canadian health professions faculty used the IASP Core Curriculum to develop an integrated interprofessional pain curriculum and applied this to prelicensure education for health care professionals in that nation [14]. As a result, Canadian students have demonstrated improved outcomes in their knowledge and beliefs about pain. Furthermore, the faculty believed that the curricula addressed several learning needs, such as improved integration of knowledge with clinical decision-making [15]. The available IASP curricula were uniprofessional until 2012 when its prior curricula for each profession were updated and a separate interprofessional curriculum was developed [16]. These advances in pain-related curricula took place concurrent with innovations in the educational process and evolving paradigms for teaching and learning. Such advances and innovations have reduced the prior emphasis upon factual knowledge that learners are expected to acquire, and increased the emphasis placed upon students' capacity to act effectively in complex, diverse, and variable situations [17].

The desired outcomes of the educational process, competency-based education (CBE), emphasizes the learner's capacity to successfully carry out tasks in the real world, rather than the capacity to absorb and recite content [18]. CBE focuses on the desired performance characteristics of health care professionals [18], as opposed to what or how learners are taught. Thus, CBE shifts the metrics for judging the effectiveness of educational programs toward assessing the practical impact of education instead of simply its content or process [18].

The emphasis of CBE on outcomes of pain education echoes the rise of outcomes assessment more broadly in health care [19]. The call for outcomes assessment as an integral part of person-centered pain care followed widespread recognition that the quality of care is not improved simply by accumulating and disseminating the best available evidence [20–22]. Instead, excellence in person-centered care requires that clinicians respond to patients' needs and preferences in a compassionate, knowledgeable, and coordinated fashion [23]. Assessment of competencies is more closely aligned with the reality (i.e., quality) of clinical care than is assessment of knowledge alone. Thus, both in the education of entry-level health care professionals, as well as in the modification of postgraduate clinician behavior, a shift toward assessment of quality and outcomes of care has given rise to a need to associate curricular content with competencies.

Inadequate education of health care professionals is a major and persistent barrier to safe and effective pain management. Despite the health professions' development of competencies in pain management for advanced learners [24], special populations [25], and specific types of pain [26], as well as the myriad guidelines and position articles on pain management issued by numerous professional bodies representing thousands of clinicians [27], core pain management competencies for prelicensure entry-level health professional learners have not yet been established. The absence of core competencies may in part be a reason for the paucity of pain education found in undergraduate programs. The limited pain education that is currently provided may be ineffective because it focuses on traditional impersonal topics such as anatomy and physiology that may have little direct relevance to the complex daily problems faced by patients, families, and clinicians [28].

A noteworthy and relevant trend in health care education is the recognition that increased collaboration and teamwork are necessary to improve the quality and safety of health care [29]. The IOM, World Health Organization, and numerous professional groups envisage interprofessional education as an important part of preparing a workforce to practice collaboratively at a time when the number of patients with complex, long-term medical problems is expanding at an unprecedented rate [29]. The shift from multidisciplinary/multiprofessional to interprofessional team pain care resonates perfectly with the present emphasis upon interprofessional education and practice.

To help bridge the gap between the compelling needs of persons in pain and the skills, knowledge, and values of the interprofessional health care team, a group of educators and clinicians was convened to undertake a structured interprofessional consensus process in order to develop core pain management competencies appropriate for prelicensure health care providers. Annex 1 includes a list of professions represented at the summit. "Prelicensure education" refers to the training period prior to obtaining initial licensure to practice in the chosen profession. Prelicensure education was chosen because it represents the foundational period of entry-level health professional education; however, application of these competencies may be relevant to clinical learners well beyond prelicensure training (e.g., post-licensure training or continuing education). Within an interprofessional team delivering person-centered care, each profession will carry out roles that require both common knowledge and specific educational content to support achieving competencies in a manner consistent with each profession's scope, emphasis, and role in health care.

Methods

The structured process for identifying pain management core competencies for prelicensure learners took place in two phases from October 2011 through November 2012. During Phase I (October–July), an executive committee (EC) comprised of seven experts in pain management and education synthesized current evidence and existing profession-based competencies to develop a draft set of candidate competencies. During Phase II

(August–November), an international competency advisory committee (CAC) of 22 members representing 10 professions reviewed all draft materials and then met in-person to finalize the draft materials and recommend a final set of consensus-based competencies.

Phase I

The EC included seven leaders from multiple professions who collectively brought expertise in pain management, education science, and development of evidence-based consensus. This group collaborated over 10 months to identify literature and other relevant material for review, define key terms, and identify individuals to participate in the interprofessional summit as part of a CAC. The EC defined the initial structure and draft content of the competencies, as well as the topics and goals of the summit.

During Phase I, the EC examined the current state of existing core competencies and pain management education for health professional learners. Recommendations of key publications, existing curricula, and core competencies were solicited from members of the EC as well as from other key content experts. Foundational references identified from these sources served as a starting point for a literature review.

Electronic journal databases were searched using Pubmed and CINAHL. A partial list of search terms and other researched sources is included as Annex 2. The search strategy used pain-related terms (e.g., pain, pain management) in combination with education-related terms such as competency/competency-based education and curriculum. Health profession terms (e.g., medicine, nursing) and concepts such as consensus building and interprofessional education were also explored. The search was limited to English language articles. Emphasis was placed on identifying content focused on prelicensure learners, but not limited to that group. Moreover, an internet search using the Google search engine identified grey literature that was produced by government, academia, business, and industry sources to identify existing competencies, curricula, educational programs, and clinical guidelines on pain management. Grey literature refers to written material including reports that are difficult to access via conventional channels such as published journals but is considered an important source of information because it tends to be original and recent [30]. This search identified multiple existing pain management curricula, as well as established competencies in related fields. A document produced by a group assembled by the American Geriatrics Society, "Multidisciplinary Competencies in the Care of Older Adults at the Completion of the Entry-Level Health Professional Degree" was employed as a template through the development process [31]. Finally, a search was conducted of the following professional associations' Websites: American Academy of Pain Medicine, American Chronic Pain Association, American Pain Society, American Society for Pain Management Nursing, and IASP.

A comprehensive list of source material was created that included peer-reviewed and grey literature of existing curricula, competencies, and clinical guidelines. The EC identified and analyzed themes and key content of each source. Themes were grouped into the following basic categories as a starting point: What is pain? What is the context of pain? What does pain look like? What affects pain? How is pain relieved? The EC identified a natural and synergistic link with the topic areas addressed in the 2012 revised curricula prepared by the IASP [16] and mapped the domains to those topic areas (i.e., multidimensional nature of pain, pain assessment and measurement, management of pain, clinical conditions). The EC went on to review several iterations of the competencies and develop a list of 40 draft competencies under the four domains for the CAC to review and critique during the consensus summit.

Phase II

The 29-person Expert Interprofessional Pain Competencies Consensus Group assembled for the summit included both the EC and the CAC members. The group members brought experience in clinical pain management; research and education in pain management; education science; curriculum development; interprofessional education and teamwork; and knowledge uptake. All group members were from the United States and Canada. A particular effort was made to include individuals who were active in pain management professional associations and other stakeholder groups. A full list of members is included in Annex 3. Veterinary medicine was included because of evidence from Canada suggesting that veterinary medicine students receive more extensive and effective prelicensure education on pain than other prelicensure health professionals and because of the extensive experience of these clinicians in treating nonverbal patients [5].

The EC provided the CAC members with a synthesis of the literature on competencies in pain management across the health professions for review. The group then convened for a 2-day *Summit for Interprofessional Consensus on Pain Management Competencies* in Sacramento, California, in August 2012. Each participant disclosed potential conflicts of interest and agreed to contribute feedback that was independent and objective. Members of the EC led the summit. The group reviewed the central concepts of CBE and agreed upon key terms to establish a common understanding of nomenclature before embarking on a critique of the draft documents and subsequent consensus building. The initial compilation of 40 draft competencies under the four domains were reviewed as a full group before beginning a series of small group discussions led by EC members utilizing the World-Café™ [32] model. This method offered each participant the opportunity to evaluate and respond to each of the initial competencies through a focused 20-minute dialogue with four to five other CAC members. The EC randomly assigned CAC members to four groups. Every group rotated through each of the four rooms, thereby

allowing every CAC member to comment on all four domains and its associated competencies.

Following the WorldCafe™ sessions, the full summit group reassembled to review and discuss each domain including all the comments and findings collected from each group. A list of key terms and a set of core values that are embedded throughout the domains were also identified on Day 1. After the full group discussion, the EC met to synthesize and refine the competencies and presented a revised list to the full group at the beginning of the second day of the summit. An open voting process was used to confirm consensus among the full group on the content and structure of the domains and competencies.

Following the summit, EC members incorporated CBE terminology, reduced redundancies, and clarified language. The updated domains and competencies were sent to the CAC for review and refinement in October 2012. The final document reflects consensus on the review and endorsement of the core values, competencies, and definitions of key terms.

Results

From the initial 40 draft competencies, 25 competencies applied to pain assessment and management were supported by the close of the summit. EC members further condensed the list to reduce redundancies within domains as well as to refine final competencies. The final list included 21 pain assessment and management core competencies under four domains. The competencies are outcome based and focus on actions health professional students should be able to perform in a variety of complex situations prior to completion of prelicensure training.

The first three domains address 1) the concepts and complexity of pain; 2) pain assessment; and 3) collaborative approaches to treatment. These domains highlight the foundational skills and knowledge each clinician should possess to identify, assess, and treat pain. The fourth domain focuses on the application of effective pain management in various populations and contexts. The full list of domains and competencies are listed in Box 1.

During the course of discussions, core values that are integral to and embedded within each domain were identified. Participants felt that certain other principles, such as advocacy, collaboration, compassion, effective communication, and evidence-based practice, were relevant to all domains and competencies. Participants came to a consensus on the set of core values and principles that should be considered and incorporated into the development of pain management curricula and learning activities. The set of all core values/principles is presented in Box 2.

The full summit group also stressed the importance of clearly defining key terms relevant to pain management and related competencies: pain, advocacy, comprehensive care, cultural inclusiveness, evidence-based practice, interprofessional teamwork, professional competencies, and social support system.

Several terms related to analgesia such as addiction, adherence, and misuse were also discussed at length. The group believed that these terms should be clearly defined as a resource for curriculum development. These terms, as well as many others, are provided on the project Website (http://www.ucdmc.ucdavis.edu/paineducation) and in the instructional resource material produced during the next phase of the project.

Discussion

Through an interprofessional consensus process, core competencies in pain assessment and management (Box 1) were developed to address prelicensure pain management education in all major health care professions. These core competencies are consistent with the domain outline from the IASP pain curricula [16]. Introducing pain education early in the preparation of health professionals emphasizes the value of improving quality of life and creates the potential to instill critical competencies that support the humanistic aspects of health care. Moreover, early education related to pain offers the opportunity to reverse the disparity between what students are taught and what they face in practice related to pain. Continuing to ignore pain as a substantial and critical part of the curriculum for health professionals stands in stark contrast to the importance of pain in society; that pain is the most common reason a person seeks clinical care; that under-treated, over-treated, or ineffectively treated pain greatly impacts major public health problems such as disability, prescription drug abuse, or the overall cost of health care; and that the cost of pain in terms of suffering is vast but immeasurable.

Although no comprehensive survey regarding pain education curricula across health care professions has been conducted in the United States, available evidence indicates that pain management training is widely inadequate across all disciplines [2,4–6,8,10–12]. A survey of undergraduate pain curricula for health care professionals in the United Kingdom found pain education content for undergraduate health care professionals to be nominal and fragmented, accounting for less than 1% of program hours for some disciplines [4]. A survey of Canadian prelicensure pain curricula for dentistry, medicine, nursing, occupational therapy, pharmacy, and physiotherapy students found that respondents representing the majority (67.5%) of health science programs could not specify designated hours for pain course content or clinical conferences [5]. Veterinary medicine curricula were also surveyed for comparison and had five times more pain content than did medicine [5]. The minimal number of designated pain hours is not surprising as a recent examination of Canadian requirements for nine entry-to-practice health science professions

Box 1 Pain management domains and core competencies

Domain one
Multidimensional nature of pain: What is pain?
This domain focuses on the fundamental concepts of pain including the science, nomenclature, and experience of pain, and pain's impact on the individual and society.

1. Explain the complex, multidimensional, and individual-specific nature of pain.
2. Present theories and science for understanding pain.
3. Define terminology for describing pain and associated conditions.
4. Describe the impact of pain on society.
5. Explain how cultural, institutional, societal, and regulatory influences affect assessment and management of pain.

Domain two
Pain assessment and measurement: How is pain recognized?
This domain relates to how pain is assessed, quantified, and communicated, in addition to how the individual, the health system, and society affect these activities.

1. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.
2. Describe patient, provider, and system factors that can facilitate or interfere with effective pain assessment and management.
3. Assess patient preferences and values to determine pain-related goals and priorities.
4. Demonstrate empathic and compassionate communication during pain assessment.

Domain three
Management of pain: How is pain relieved?
This domain focuses on collaborative approaches to decision-making, diversity of treatment options, the importance of patient agency, risk management, flexibility in care, and treatment based on appropriate understanding of the clinical condition.

1. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.
2. Identify pain treatment options that can be accessed in a comprehensive pain management plan.
3. Explain how health promotion and self-management strategies are important to the management of pain.
4. Develop a pain treatment plan based on benefits and risks of available treatments.
5. Monitor effects of pain management approaches to adjust the plan of care as needed.
6. Differentiate physical dependence, substance use disorder, misuse, tolerance, addiction, and nonadherence.
7. Develop a treatment plan that takes into account the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.

Domain four
Clinical conditions: How does context influence pain management?
This domain focuses on the role of the clinician in the application of the competencies developed in domains 1–3 and in the context of varied patient populations, settings, and care teams.

1. Describe the unique pain assessment and management needs of special populations.
2. Explain how to assess and manage pain across settings and transitions of care.
3. Describe the role, scope of practice, and contribution of the different professions within a pain management care team.
4. Implement an individualized pain management plan that integrates the perspectives of patients, their social support systems, and health care providers in the context of available resources.
5. Describe the role of the clinician as an advocate in assisting patients to meet treatment goals.

found pain competencies for only nursing (N = 9) and dentistry (N = 2) [32].

Limited data exist to clearly gauge the state of pain education in each individual profession; however, a review of available findings suggests in no instances are the offerings robust. A recent survey of pain-related content in educational institutions worldwide found that in spite of many achievements, medical school education in acute pain management was inadequate [12]. The First National Pain Medicine Summit, convened in November 2009 by the American Medical Association's Pain and Palliative Medicine Specialty Section Council, found that training was poor or "not leading to competency" at both the undergraduate and residency levels [33]. A recent study of 117 medical schools in the United States and Canada

Box 2 Core values/principles

- Advocacy
- Collaboration
- Communication
- Compassion
- Comprehensive care
- Cultural inclusiveness
- Empathy
- Ethical treatment
- Evidence-based practice
- Health disparities reduction
- Interprofessional teamwork
- Patient-centered care

found that only four U.S. schools offered a required course on pain [6]. A survey of 111 attending physicians, residents, nurse practitioners, and physician assistants working in community clinics all reported their pain management training as less than adequate [7]. In a study of faculty within 16 U.S. Midwestern schools of nursing, approximately three fourths (72.9%) of the participants recalled being taught about pain management; but a minority (36.5%) believed that they were adequately prepared on the topic [9]. In a faculty survey of accredited physical therapy education programs in North America, the most frequently reported amount of time spent on pain in the curriculum was 4 hours [8]. The authors of a study designed to describe how and in what depth pain management is covered in U.S. pharmacy school curricula concluded that the topic of pain management is inadequately developed and poorly presented in many schools [10]. Pain management, particularly for acute and postoperative pain, remains a core curriculum component in dentistry; yet, predoctoral and continuing education programs in chronic orofacial pain are limited [2]. Despite efforts to address the need for professional education in pain management for psychologists [34], psychology training programs have been slow to adopt competency-based training in pain management [2]. Data on the pain management training received by practitioners of complementary and alternative medicine are limited, but there are substantial variations found in pain education among chiropractors and acupuncturists [11].

This interprofessional consensus process was an inclusive endeavor, capitalizing on expertise from professionals with widely diverse backgrounds related to pain management. Through iterative review, including discussions and identification of central issues of agreement and disagreement, this systematic and collaborative process achieved a cohesive outcome. The process complemented efforts of the IASP to revise uniprofessional curricula and develop interprofessional curricular content. The active participation of members of the IASP Education Initiatives Working Group and the Chair of the subgroup that developed IASP's Interprofessional Pain Curriculum Outline [J. W.-W.] supported communication between, and alignment of, the two undertakings. Consequently, the competencies produced by this project parallel the structure of the interprofessional and uniprofessional pain curricula developed by IASP for various professions [16].

Our process and the resultant competencies have limitations. Although the panel members were chosen to achieve diversity and broad expertise, its composition may neither adequately represent the full spectrum of professions involved in pain management nor all views held by individuals within a single profession. The competencies are inclusive of a wide range of populations, settings, and conditions; however, additional competencies are necessary for other subpopulations such as children, older persons, or individuals with special cultural considerations that were not addressed in this initial effort. Moreover, the evidence review was limited to English language publications. While the competencies could serve as a global resource, their origin from a strongly North American perspective leaves open the need for adaptation to other languages, cultures, and value systems, as well as consideration of other national and regional concerns. In the absence of scientific evidence or endorsed professional standards, the expert panel rendered opinion that was ratified by consensus. As such, these competencies may help to bridge the gap between knowledge, learning, and clinical performance.

The panel faced a number of challenges. An early challenge was in defining the terms "interprofessional" (applying to health professions learning together) and "competency" (focusing on measurable outcomes of learning). In order to define competencies that were applicable across clinical professions involved in pain management, assembling a panel from diverse professions and disciplines was critical, but represented a challenge given the distinct perspectives and areas of clinical expertise of the participants. The in-person meeting with small and large group discussions, and use of a consensus facilitator helped participants work with various perspectives and aided identifying areas of consensus. Defining competencies related to the areas of evaluation and management was also challenging because learners in differing stages of training may have little or no direct clinical care, and different professions vary in their exposure of students to individuals with pain and their support systems. Our group therefore focused on core concepts necessary to effectively address pain and left implementation, including methods of teaching and evaluation, to users of the competencies. We also found it challenging to define the competencies in ways that would be measurable. Inclusion of experts in education and curriculum development was critical for reframing a number of the competencies in ways that facilitated measurement. Finally, the initial list of competencies generated by the group was quite lengthy. An iterative, consensus-building process facilitated defining a more concise "core" set of competencies. Nonetheless, it is our hope that these competencies will undergo further rigorous examination and refinement.

Although the need for basic expected competencies in pain management seems obvious, to our knowledge, these core competencies represent the first of their kind. Much work is needed to integrate the competencies into the education of health professionals and to evaluate

impact. The domains and competencies are offered as a model and starting point for prelicensure pain management education in all health care professions. Developing these core competencies required focus on a specific period of clinical education and the prelicensure period was felt to be an important starting point; however, these competencies may be applicable to post-licensure education as well. They are neither exhaustive nor tailored to the specific needs of any one profession. Instead, they represent a minimum standard that may be variably emphasized in each educational undertaking, depending on each profession's unique needs, roles, and expectations as well as those for each educational program and institution.

We urge licensure, accreditation, certification, education, and policy governing bodies to engage in this important process and to consider these competencies when establishing standards. Curriculum developers across the health sciences are encouraged to evaluate their current educational content and adopt and test these competencies. It is envisioned that the competencies will be incorporated into learning activities that will be implemented through a myriad of didactic and case-based learning opportunities woven throughout the formative stages of professional development for future health care students. Exactly how these core competencies will be incorporated into diverse curricula within and across all health professions is not clear and will likely differ between professions. Mapping these competencies with existing curricula may help identify gaps or areas for improvement. They also offer a means of analyzing whether or not health professional curricula cover critical content related to pain assessment and management, and help guide curricular outcomes in this area.

Conclusions

These consensus-based core competencies for pain management provide a basis for improving the culture and context of care for adults and children with acute and chronic pain or pain at end of life. They apply to all major clinical professions involved with pain management, although they target prelicensure education they apply across the spectrum from prelicensure to continuing education.

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Annex 1 Professions represented at the pain management competencies summit

Profession
Acupuncture
Dentistry
Education science
Medicine
Nursing
Pharmacy
Physical therapy
Psychology
Social work
Veterinary medicine

Annex 2 Literature review terms and other resources

Electronic databases search terms
- Clinical competence
- Acupuncture/education
- Competency-based education
- Curriculum
- Education
- Education, dental
- Education, medical
- Education, medical, undergraduate
- Education, nursing, baccalaureate
- Education, nursing, graduate
- Education, pharmacy
- Educational status
- Knowledge
- Models, educational
- Pain
- Pain management
- Physical therapy specialty/education
- Psychology/education
- Social work/education
- Students, dental
- Students, medical
- Students, nursing
- Students, pharmacy

Grey literature search
- Agency for Healthcare Research and Quality
- Center for Nursing Excellence in Long-Term Care, Geriatric Pain
- City of Hope Pain & Palliative Care Resource Center
- Institute of Medicine
- Interprofessional Education Collaborative
- Johns Hopkins University, School of Medicine Pain Curriculum
- Maryland Board of Nursing, Pain Management Nursing Role/Core Competency A Guide for Nurses
- Pain & Policy Studies Group (PPSG) at the University of Wisconsin Carbone Cancer Center
- Tufts University, Pain Research, Education, and Policy (PREP) program curriculum
- University of Toronto Centre for the Study of Pain
- US DHHS National Guidelines Clearinghouse
- Virginia Commonwealth University, Pain Education Curriculum

Professional associations
- American Academy of Pain Medicine
- American Association of Colleges of Nursing
- American Chronic Pain Association
- American Pain Society
- American Society for Pain Management Nursing
- Association of American Medical Colleges
- International Association for the Study of Pain

Annex 3 Expert interprofessional pain competencies consensus group

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Pain Medicine

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PROFESSIONALISM AND PERSPECTIVE

Commentary

Advancing Pain Care—Core Competencies for Pain Management

Disclosure: None to report.

The various unpleasant sensations that collectively are known as pain are among the most important means by which the body signals that it is hurt or malfunctioning, and everyone experiences pain in one form or another at least occasionally. Regrettably, many people experience pain as a regularly recurring or continuous part of their lives as a result of advanced age, injury, or chronic illness, among other reasons.

Because pain so often accompanies injury or illness, it is the overall most common symptom that causes people to consult a physician or other health care provider. And because pain is such a common and important symptom, much time and attention in health care professional training is devoted to understanding the various types of pain and to learning to recognize the diagnostic significance of the anatomic location, character, frequency, intensity, and other characteristics of pain. Indeed, we are taught that the nature of one's pain in and of itself can be largely diagnostic of some conditions. In stark contrast, relatively scant attention in health care professional training is given to understanding how to successfully manage pain in its many forms and contexts.

The lack of attention to managing pain in health care professional training is perplexing given the frequency of pain as a symptom and the large number of people who would benefit from effective pain management. An estimated 100 million American adults suffer pain on a regular basis [1], at a staggering annual cost of more than $600 billion [2]. The lack of attention to pain management in health care professional training is further perplexing in so far as relief of pain has been one of the most fundamental and transcendent responsibilities of physicians and other health care professionals in all cultures throughout history.

In this issue of *Pain Medicine*, Fishman and colleagues report the results of an interprofessional consensus development process that has produced for the first time a clear delineation of core competencies in pain assessment and management for prelicensure health professional education [3]. These competencies are logically and strategically categorized into four domains: 1) the multidimensional nature of pain, 2) assessment and measurement of pain, 3) management of pain, and 4) the context of pain management. Promulgation of these pain management core competencies represents a major milestone in advancing pain care that should be widely applauded for multiple reasons.

First, these core competencies address an important population health problem that is currently inadequately addressed in the curricula of medical, nursing, pharmacy, and other health care professional training. As noted by Fishman and colleagues, pain management education in prelicensure learning is fragmented, inconsistent, and seemingly ineffective [4–7]. This fragmentation and lack of standardization has led to disparate pain care and poor pain outcomes in vulnerable populations [8,9]. Paradoxically, while pain is both widely undertreated and unequally treated in the United States today, as a nation we have the highest level of opioid use in the world [10]. Such poor pain management outcomes have elicited calls for an educational roadmap that crosses professions and educational levels to promote equitable pain care [11]. The lack of such a roadmap undoubtedly has been a significant contributing factor to the current epidemic of prescription opiate abuse [12,13]. The core competencies in pain management advanced by Fishman and colleagues provide the template for a pain management educational roadmap that should lead to more predictable and consistent higher quality care.

Second, these pain management competencies were developed by an interdisciplinary consortium and have a clear interdisciplinary focus. As such, they better simulate the realities of health care practice than the generally siloed approach to health care professional training prevalent today.

Pain is a health problem whose context and management are influenced by myriad stakeholders, including health care practitioners, community-based and professional organizations, policy makers, regulatory and accrediting bodies, business and industry, health care payers, and advocacy groups. The diversity of stakeholders involved in pain care has led to laudable improvements in recognition and diagnosis of pain, processes of clinical care, and treatment technologies, including pharmaceutical products. However, too often these advances have been achieved without understanding and agreement among stakeholders on how to prepare the health care workforce

to operationalize them in a way that delivers better care. Fishman and colleagues offer an important starting point from which to begin addressing these gaps.

Third, a competency-based approach to health care professional education provides clear goals for what is important to accomplish in pain care, while not being prescriptive about how to achieve the competencies necessary to achieve the desired outcomes. This gives educators flexibility in accomplishing the requisite learning. A competency-based approach to learning overtly recognizes the complexity of health care and health care professional training, and that there is no single pathway for reaching the desired destination. Further, a competency-based approach recognizes the evolving and ever-changing nature of medical science, clinical care guidelines, and diagnostic and therapeutic technologies.

Fourth, these competencies are directed at prelicensure trainees and thus are aimed at an especially impressionable and important time in professional maturation that reasonably can be expected to establish a solid foundation for pain management in whatever further training the practitioner pursues. Similarly, as health care delivery increasingly moves toward team-based care, it is important that trainees be prepared to practice in an interprofessional milieu that will increasingly be the norm. The need for interprofessionality is tangibly recognized and addressed in these competencies.

Fifth, the core competencies are grounded on a set of principles and values. In an area as complex and nuanced as pain management, the importance of having clearly understood and shared values cannot be overstated. Values provide a critically important compass for finding one's direction in uncertain or confusing situations, as so often is the case in pain management.

The pain management core competencies developed by Fishman and colleagues fill an important void in health care professional training and are long overdue. If utilized as intended, these competencies should lead to the development of a health care workforce having demonstrated competence in caring for patients in pain, higher performing health care systems, and improved health care outcomes. The process used to develop these core competencies also provides a model for how health care professional curricula might be better developed for other complex population health problems such as obesity management, hypertension, health care-associated infections, and patient safety, to name some.

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PAIN MANAGEMENT CORE COMPETENCIES FOR PRELICENSURE CLINICAL EDUCATION

An Interprofessional Consensus

PURPOSE

To develop core competencies in pain management for prelicensure clinical education for all health professions as a basis for delivering comprehensive and high-quality pain care.

PROCESS

The core competencies and supporting core values and principles were developed by an interprofessional expert group comprised of leaders from multiple health professions, including: dentistry, medicine, nursing, pharmacy, physical therapy, psychology, social work, acupuncture and veterinary medicine. The domains are aligned with the outline categories of the International Association for the Study of Pain curricula.

CORE VALUES/PRINCIPLES

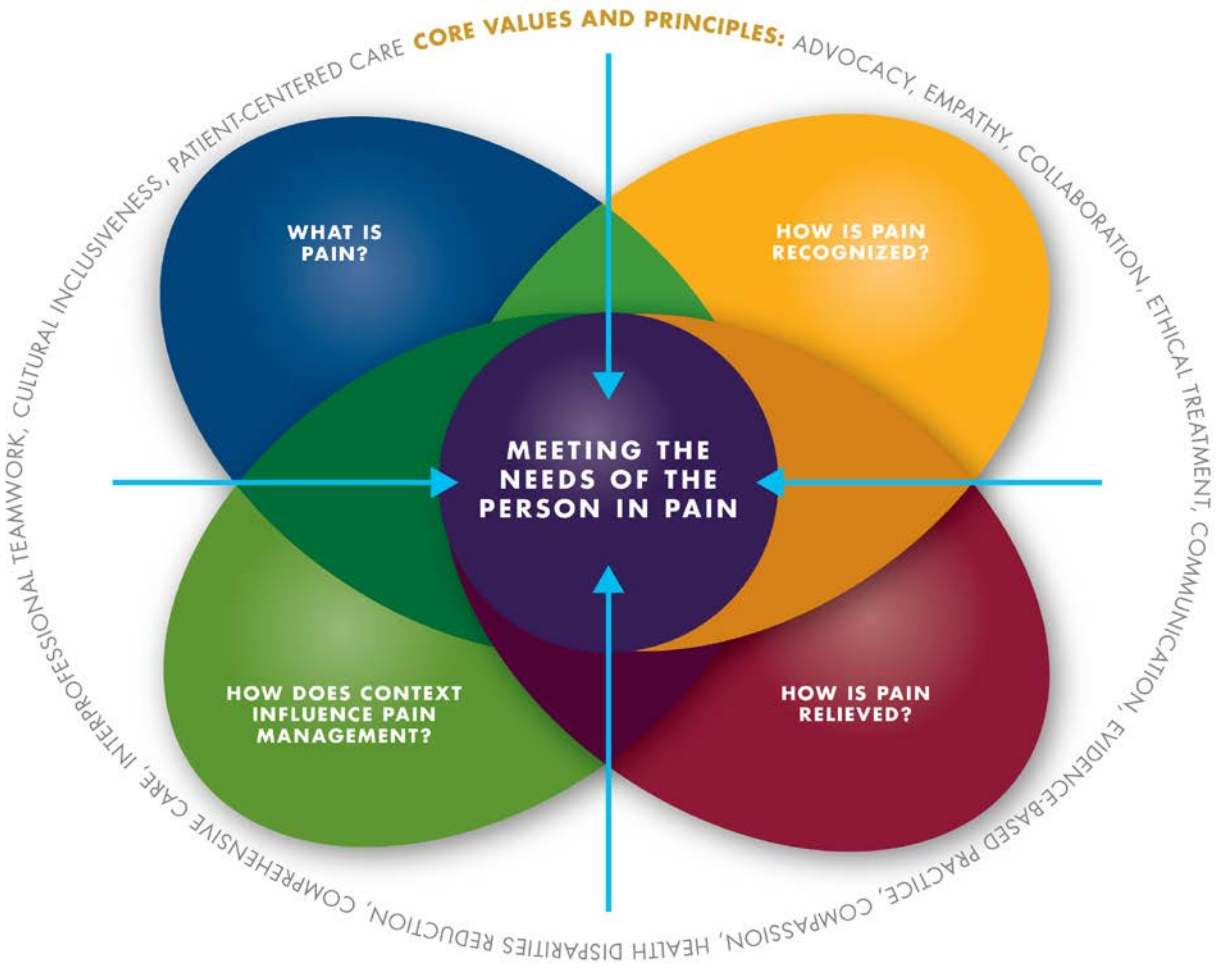
The following core values and principles are integral to and embedded within all domains and competencies. To deliver the highest quality of care, health professionals must be able to determine and address the needs of patients from a variety of cultures and socio-economic backgrounds; advocate for patients on individual, system and policy levels; and communicate effectively with patients, families and professionals. These principles transcend any single domain and reflect the need for evidence-based comprehensive pain care that is patient centered and is delivered in a collaborative, team-based environment.

- Advocacy
- Collaboration
- Communication
- Compassion
- Comprehensive Care
- Cultural Inclusiveness
- Empathy
- Ethical Treatment
- Evidence-Based Practice
- Health Disparities Reduction
- Interprofessional Teamwork
- Patient-Centered Care

DOMAINS

The pain management core competencies are categorized within four domains: multidimensional nature of pain, pain assessment and measurement; management of pain, and context of pain management. The competencies address the fundamental concepts and complexity of pain; how pain is observed; collaborative approaches to treatment options; and application of competencies in the context of various settings, populations and care teams.

Pain Management Core Competencies



Domain One
Multidimensional Nature of Pain: What is Pain?

This domain focuses on the fundamental concepts of pain including the science, nomenclature, experience of pain, and pain's impact on the individual and society.

1. Explain the complex, multidimensional and individual-specific nature of pain.
2. Present theories and science for understanding pain.
3. Define terminology for describing pain and associated conditions.
4. Describe the impact of pain on society.
5. Explain how cultural, institutional, societal and regulatory influences affect assessment and management of pain.

Domain Two
Pain Assessment and Measurement: How is Pain Recognized?

This domain relates to how pain is assessed, quantified, and communicated, in addition to how the individual, the health system, and society affect these activities.

1. Use valid and reliable tools for measuring pain and associated symptoms to assess and reassess related outcomes as appropriate for the clinical context and population.
2. Describe patient, provider and system factors that can facilitate or interfere with effective pain assessment and management.
3. Assess patient preferences and values to determine pain-related goals and priorities.
4. Demonstrate empathic and compassionate communication during pain assessment.

Domain Three
Management of Pain: How is Pain Relieved?

This domain focuses on collaborative approaches to decision making, diversity of treatment options, the importance of patient agency, risk management, flexibility in care, and treatment based on appropriate understanding of the clinical condition.

1. Demonstrate the inclusion of patient and others, as appropriate, in the education and shared decision-making process for pain care.
2. Identify pain treatment options that can be accessed in a comprehensive pain management plan.
3. Explain how health promotion and self-management strategies are important to the management of pain.
4. Develop a pain treatment plan based on benefits and risks of available treatments.
5. Monitor effects of pain management approaches to adjust the plan of care as needed.
6. Differentiate physical dependence, substance use disorder, misuse, tolerance, addiction, and non-adherence.
7. Develop a treatment plan that takes into account the differences between acute pain, acute-on-chronic pain, chronic/persistent pain, and pain at the end of life.

Domain Four
Clinical Conditions: How Does Context Influence Pain Management?

This domain focuses on the role of the clinician in the application of the competencies developed in Domains 1-3 and in the context of varied patient populations, settings, and care teams.

1. Describe the unique pain assessment and management needs of special populations.
2. Explain how to assess and manage pain across settings and transitions of care.
3. Describe the role, scope of practice and contribution of the different professions within a pain management care team.
4. Implement an individualized pain management plan that integrates the perspectives of patients, their social support systems and health care providers in the context of available resources.
5. Describe the role of the clinician as an advocate in assisting patients to meet treatment goals.

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THE MAYDAY FUND

Professional Boundaries in the Physician-Patient Relationship

Glen O. Gabbard, MD, Carol Nadelson, MD

THE SUBJECT of professional boundaries (and boundary violations) has received a great deal of recent attention in the psychiatric literature.[1-5] The emphasis on defining guidelines for professional conduct has expanded beyond the confines of ethics committees and has worked its way into licensing boards charged with disciplining physicians whose behavior jeopardizes the well-being of patients. The Massachusetts Board of Registration in Medicine,[6] for example, has recently issued detailed guidelines on such matters as self-disclosure, dual relationships, sexual relationships with patients, and other professional boundaries to help define for the public and for the profession the parameters of professional conduct in the practice of psychotherapy by physicians. While specialists in psychiatry have been debating the pros and cons of issuing such guidelines, nonpsychiatric physicians have yet to involve themselves so extensively in similar discussions. In this article, we will provide a conceptual framework for discussion of professional boundaries in the physician-patient relationship and offer our view of measures the profession can take to prevent serious violations of these boundaries. We will use instances from our own clinical experiences or those of our trainees to illustrate the relevant issues.

WHAT ARE BOUNDARIES?

Professional boundaries in medical practice are not well defined. In general, they are the parameters that describe the limits of a fiduciary relationship in which one person (a patient) entrusts his or her welfare to another (a physician), to whom a fee is paid for the provision of a service. Boundaries imply professional distance and respect, which, of course, includes refraining from sexual involvement with patients. While sexual contact is perhaps the most extreme form of boundary violation, many other physician behaviors may exploit the dependency of the patient on the physician and the inherent power differential. These include dual relationships, business transactions, certain gifts and services, some forms of language use, some types of physical contact, time and duration of appointments, location of appointments, mishandling of fees, and misuses of the physical examination. The transgressions of some of these boundaries may at times be necessary and helpful. For example, it would certainly be appropriate to hold the hand of a patient who reaches out to a physician after losing a family member. One can differentiate minor boundary crossings from devastating boundary violations that ruin professional careers and seriously damage patients.[3] Similarly, some problems arise from corrupt and unethical physician behavior, while others arise from honest misunderstandings.

Much of the medical profession's increased interest in boundaries has derived from the awareness of the damaging effects of sexual misconduct. Examination of instances of physician-patient sexual relationships has revealed that sexual exploitation is usually preceded by a progressive series of nonsexual boundary violations, a phenomenon generally described as the "slippery slope."[2,3,7] In this regard, what appear to be trivial violations may in reality be considerably more serious when viewed in the context of a continuum. Attention to nonsexual boundary issues may therefore be an effective way to prevent sexual boundary transgressions. This approach is especially salient because it has become clear that many of the nonsexual boundary violations may in and of themselves cause harm to patients irrespective of the possibility that they also may lead to sexual involvement.[1,3-5]

As a result of the intense concern that has been generated by sexual exploitation in the physician-patient relationship, much more research has accumulated on sexual boundary violations than on nonsexual boundary violations. Hence, our discussion of professional boundaries will begin with a consideration of sexual misconduct and progress from there to an examination of other forms of professional boundary transgressions.

Sexual Boundary Violations

Six studies[8-13] have sought to determine the prevalence of sexual misconduct in the physician-patient relationship (Table).

A comparison of the US studies with the survey from the Netherlands and with the studies from Canada suggest that the problem is one that is not unique to US physicians and that it occurs with roughly the same frequency in the United States as in other countries where sexual misconduct has been studied. The problem is not unique to medicine. Other professions are also vulnerable, including other health care professionals, the clergy, and the law. Research aimed at psychologists, social workers, and teachers reveals that sexual exploitation is a pervasive problem in fiduciary relationships.[2,14-16]

The studies listed in the Table must be viewed as less than definitive because of the fundamental methodological problems inherent in questionnaire surveys. These include low return rates, raising the possibility that the sample is by no means representative. Other problems include the possibility that some practitioners might not answer the questions honestly because they question the anonymity of the method. Also, some who have engaged in sexual misconduct may not return the questionnaire. On the other hand, other professionals who have transgressed sexual boundaries might feel the need to anonymously confess. In essence, we do not know the true prevalence of sexual misconduct.

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Self-report Surveys of Sexual Contacts Between Physicians and Patients

Source, y	Sample Size	Specialties	Return Rate, %	Men Acknowledging Contact, %	Women Acknowledging Contact, %
Kardener et al,[8] 1973	1000 male physicians	Gynecology, psychiatry, internal medicine, surgery, general practice	46	12	Not applicable
Gartrell et al,[9] 1986	5574	Psychiatry	26	7.1	3.1
Gartrell et al,[10] 1992	10 000	Family practice, internal medicine, gynecology, surgery	19	10	4
College of Physicians and Surgeons of British Columbia,[11] 1992	2082	All specialties	69.5	3.8 (8.1*)	0.3 (4.3*)
Wilbers et al,[12] 1992	975	Gynecology, ENT	74	4	4†
Lamont and Woodward,[13] 1994	792	Gynecology	78	3	1

*Percentage of sexual contacts with former patients.
†This figure is for gynecologists. Only five female ear, nose, and throat (ENT) specialists were in the study.

While the data suggest that sex between a male physician and a female patient is the most common, all gender configurations also are seen with some regularity. In a series of more than 2000 cases of therapist-patient sex, Schoener et al[17] noted that approximately 20% of cases involved a same-sex dyad, and 20% of the therapists were women (some overlap was present in these two groups).

Concern about sexual exploitation by physicians in Canada has resulted in major task force reports in British Columbia,[11] Alberta,[18] and Ontario.[19] In the United States, the American Medical Association (AMA) Council on Ethical and Judicial Affairs considered the problem extensively and issued a 1991 statement: "Sexual contact or romantic relationships concurrent with the physician-patient relationship may be unethical."[20(p2741)]

The ethics standard proposed by the Council subsumes a wide range of situations encountered in medical practice. These would include, but would not be limited to, the following categories:

1. Predatory physicians with serious personality disorders who systematically attempt to seduce patients.
2. Those who claim to use sex for therapeutic purposes.
3. Cases involving abuse of the physical examination procedure (eg, a physician who does a breast or pelvic examination when not indicated, or a physician who does an appropriate examination in an inappropriate, erotized manner).
4. Situations in which a physician asks a patient on a date during the initial visit to his or her office or to an emergency department.
5. Cases in which a long-standing physician-patient relationship evolves into an intense lovesickness or infatuation.
6. Situations in which a rural general practitioner who is the only physician in town dates a patient because virtually anyone who is a potential romantic partner is also a patient.
7. Cases in which patients are raped or fondled (while awake or under anesthesia) in the operating room or office.
8. Cases related to sexual harassment in which the physician makes erotic or suggestive comments to the patient.

The Medical Council of New Zealand[21] has recognized the spectrum of sexual misconduct by dividing the behaviors into three categories: (1) sexual impropriety, (2) sexual transgression, and (3) sexual violation.

Sexual impropriety refers to expressions or gestures that are disrespectful to the patient's privacy and sexually demeaning to the patient. This category would include such behaviors as inappropriate draping practices, sexualized comments made by a physician to a patient, or sexually demeaning remarks about a patient's body or undergarments.

Sexual impropriety as defined by the Medical Council of New Zealand would also include instances of sexual harassment. According to the US Equal Employment Opportunity Commission,[22] any unwanted and repeated verbal or physical advances, derogatory statements or sexually explicit remarks, or sexually discriminatory comments made by someone in the workplace is sexual harassment if the recipient is offended or humiliated and job performance suffers as a result. Although these guidelines do not apply legally outside the employment context, the situation of the physician-patient relationship involves a person in a less powerful position at risk for being subjected to harassing behavior by someone who is more powerful, the classic paradigm of sexual harassment. It is important to note that there are gender differences in the perception of sexual harassment.[23] While many male physicians may view sexual comments as humorous, a female patient or health professional observing such remarks is not as likely to view them in the same way.

The second category in the New Zealand set of definitions, sexual transgression, refers to inappropriate and sexualized touching of a patient that stops short of overt sexual relations. This category would include such items as sexualized kissing, touching of breasts or genitals when not appropriate for the physical examination, or performing a pelvic examination without gloves.

The third category, sexual violation, involves physician-patient sexual relations, regardless of who initiated the relationship, and would include genital intercourse, oral sexual relations, anal intercourse, and mutual masturbation.

Regarding sexual relationships between former patients and physicians, the AMA Council on Ethical and Judicial Affairs[20] is less absolute, implying that individualized case review is necessary to ascertain whether exploitation of a still emotionally dependent patient is involved. A one-time contact with a specialist or an emergency department physician may be quite different from an ongoing physician-patient relationship of many years' duration. However, a focus on the length of the relationship alone misses other dimensions of equal importance. For example, a patient may only see a surgeon for one procedure, but if that procedure is lifesaving, the patient may retain a persistently idealized and dependent attitude toward that surgeon, which would compromise the capacity for mutual consent. Likewise, an obstetrician may have a single contact with a patient during a difficult delivery and capture the patient's fantasy as a hero or rescuer.

These considerations lead us directly into an examination of why physician-patient sex is considered unethical. Several reasons have emerged from case law, from the deliberations of ethics committees and licensing boards, and from clinical work with patients who have been exploited by their physicians. First, it is a breach of the trust that is fundamental in a fiduciary relationship. Second, it calls into question the physician's capacity for objective professional judgment. A third reason derives from the psychological state of the patient induced by the clinical situation. Patients rapidly develop feelings toward their physicians that have been called "transference." This involves the displacement of feelings derived from past relationships

onto the current physician-patient relationship. The physician can thus be viewed as an all-knowing parent, and a great deal of power is turned over to the physician by the patient.

Brody[24] has pointed out that the physician may have greater power because of greater knowledge and skills regarding diagnosis and treatment, because of higher socioeconomic and educational status, and because of an inherent social or charismatic power. The patient, on the other hand, "gains power only by virtue of being surrounded by boundaries that the physician cannot cross without egregiously violating moral rules."[24(p62)]

The combination of transference and the power imbalance between the physician and the patient makes mutual consent, in the usual sense, highly questionable. As Johnson[25(p1550)] has stressed, those who argue that mutual consent is possible between physician and patient stand "in sharp contrast to the implied presumption of disproportionate professional control underlying the AMA's opinion on sexual misconduct." Finally, studies find that there is the potential for considerable harm to the patient as a result of such sexual relationships.[26-28]

Dual Relationships

An essential element of the physician's role is the notion that what is best for the patient must be the physician's first priority. Physicians must set aside their own needs in the service of addressing the patient's needs. Other kinds of relationships that coexist simultaneously with the physician-patient relationship have the potential to contaminate the physician's ability to focus exclusively on the patient's well-being and can impair the physician's judgment. As noted herein, patients can transfer residual longings from other relationships onto the person of the physician, and they can view the physician as parent, spouse, lover, adversary, or friend. If the physician tries to maintain both roles with the patient, objective decision making may be jeopardized. For example, financial relationships or business transactions may lead to resentment or dependency that interferes with the physician's ability to be empathic, sensitive, and selfless in the physician-patient relationship. Similarly, romantic ties or intimate friendships with patients may make it difficult for the physician to confront noncompliance with treatment or to bring up unpleasant medical information. The long-standing practice of referring family members to another physician grows out of similar considerations regarding compliance and compromised objectivity.[29] Even in the case of a rural family practitioner who treats everyone in the community, a romantic relationship that begins to develop with a patient should result in referring the patient, if possible, to another physician in a neighboring town for care.

Gifts and Services

Grateful patients often wish to show their appreciation by bringing gifts to their physician. In other instances, a patient may offer to perform services for the physician in lieu of payment or in addition to payment. A range of services, such as filing, typing, baby-sitting, and cleaning, have been offered and accepted by physicians. In some places, barter is a common form of payment when patients without insurance coverage or financial means wish to pay the physician in goods or services. An example is a farmer who gives a chicken to the physician for delivering a baby.

Different forms of barter involve different boundary issues. While the provision of poultry may not violate any significant boundaries, services that involve contact with confidential records or with the physician's family may present problems. For example, if a physician's baby is injured while a patient is baby-sitting, the physician-patient relationship may be permanently damaged. If a patient paints the physician's house, but the physician is dissatisfied with the quality of the work, the ensuing tension may also adversely affect the alliance between physician and patient.

While small gifts may represent benign boundary crossings rather than serious violations, services and more significant and expensive gifts may be problematic from two standpoints. First, gift giving may be a conscious or unconscious bribe designed to keep aggression, negative feelings, or unpleasant subjects out of the physician-patient relationship. Second, there is often a secret quid pro quo involved in performing services or bestowing a gift. As implied by the saying, "There is no free lunch," expectations arise from gifts. The same can apply to the physician who gives patients gifts or refrains from charging a fee for a particular patient. Although done with the best of intentions, the patient may feel burdened by a sense of obligation that can never be openly discussed with the physician. Similarly, physicians who receive expensive gifts may feel an obligation that influences their clinical judgment in much the same way the gifts from drug companies may.[30]

Time and Duration of Appointments

Maintaining an orderly schedule of patient appointments is an aspect of professional conduct that is often neglected. While all physicians must cancel or delay appointments periodically because of an emergency or other extenuating circumstances, some practitioners keep patients waiting while extending their time with others, perhaps those they find fascinating, charming, or attractive. The special patient may be flattered by the extra time but also may wonder which of the physician's own needs are being gratified by extending the appointment. Those patients who are kept waiting may feel their physician has utter disregard for their needs and concerns, as well as their schedules.

Related problems may occur around the time of day at which appointments are scheduled. A female patient scheduled to see her male internist at 9 PM, after the office staff have gone home, may wonder why she is being seen so late without anyone else around. She may feel sufficiently uncomfortable that she will not return to see that particular physician. It is noteworthy, in this regard, that attorneys have discovered that some cases of sexual misconduct occur with patients who are scheduled during the last appointment of the day when no one else is around. As a result, they view such scheduling as reflective of the possibility of other boundary violations.[3] In general, unless an emergency occurs, physicians are wise to see patients only during office hours with someone else in the office.

Language

An essential component of professional conduct is respect for the patient's dignity. Within this framework, the physician's language is a boundary that should not be overlooked. In general, patients feel some loss of dignity merely by being in the patient role, by having to disrobe and wear a gown, and by depending on the physician's knowledge to explain what is going on with them. Addressing patients by pet names or by first name when they are not well known to the physician may be experienced as a further loss of dignity.[31] Similarly, avoiding slang names that may be offensive also maintains a sense of professionalism and respect in the relationship.

One variant of this boundary is the use of language in a seductive or erotic way designed to make the patient uncomfortable or to sexually excite the patient. One male pediatrician told a 16-year-old female patient, "You're developing a very nice set of breasts!" The patient felt embarrassed and humiliated, and she reported the comment to her mother. When the mother called the pediatrician to complain, he defended himself by insisting that he was complimenting her. This vignette is typical of some sexual harassment scenarios mentioned

previously in which a man in a position of power may think he is being humorous or flattering, while the woman on the receiving end of the comment may feel intensely uncomfortable.

Self-disclosure

While physicians commonly chat with their patients about matters of mutual interest in an effort to build rapport and put the patient at ease, excessive self-disclosure may create difficulties for the patient and strain the rapport. A common starting point on the slippery slope to sexual involvement with a patient is a role reversal in which the physician starts disclosing personal problems to the patient. Even if revealing personal issues to a patient does not lead progressively to more extreme boundary violations, self-disclosure is itself a boundary problem because it is a misuse of the patient to satisfy one's own needs for comfort or sympathy. It is also inappropriate to try to extract care for oneself when a patient is paying for the physician's time. Moreover, the patient may find sharing health concerns extremely difficult if the physician is perceived as needy and vulnerable.

The Physical Examination

Patients are often anxious and uncomfortable during a physical examination but willingly go along with whatever the physician asks them to do. One female patient seeing her physician for a sore throat submitted to a breast examination even though she couldn't see the purpose of it. She later said that at the time of the examination she felt as though she were being raped but felt paralyzed to stop the examination. Another female patient described how her gynecologist asked her about her sexual history during a pelvic examination. She experienced the questioning as an indication that her physician was "nosy and intrusive."

At the very least, the physician should explain to the patient why examining the genitals, breasts, or other sensitive areas is necessary. If the patient hesitates, the physician should encourage questions or expressions of concern that can then be clarified, empathized with, and understood. Body areas that are draped should remain draped whenever possible. The relevance of sexual history questions also should be made clear to the patient.

What about situations in which the physician encounters sexual arousal on the patient's part while conducting a physical? One female medical student was examining an elderly male patient when she noticed that his penis was erect. She completed the examination without remarking on the erection but later consulted her clinical tutor about the situation. Her tutor explained to her that she had done precisely the right thing. The medical student commented that nothing on this subject had been taught in the classroom and that if she had not had a mentor with whom to consult, she would have continued to feel insecure about the appropriate response.

The presence of a chaperone during the physical examination may also be reassuring to the patient. However, guidelines on when to use a chaperone are not well established. While traditionally within medicine a female chaperone is present when a male physician is examining a female patient, this advice is too general and does not allow for problems that arise in other gender constellations. The use of chaperones is always a matter of good clinical judgment, but we would strongly recommend having a chaperone present in the following situations: (1) with a patient who has a known history of sexual abuse; (2) with a patient who has extreme anxiety or a psychiatric disorder; (3) with a litigious patient; (4) with a patient undergoing a pelvic examination; and (5) with a patient who for any reason raises concerns in the physician.

Some of these recommendations may be modified for long-standing patients when a good physician-patient alliance exists. A nurse who is in and out of the room during the course of the examination may be sufficient.

Physical Contact

Physical contact outside the context of the physical examination varies widely. Some physicians routinely shake the hands of their patients on greeting them, a practice that is well within the scope of professional conduct. Others hold the hand of a patient when delivering stressful news. When hugs and kisses enter into the picture, the situation becomes murkier. Some patients experience a hug or a kiss as a promise of a different kind of relationship. Maybe the physician will be a parent or lover who will make up for disappointments with others in those roles from the past. In these cases, the physician has raised false hopes in the patient, who will ultimately be disillusioned.

Other patients, particularly those with histories of sexual abuse, may experience a hug or a kiss as an assault, a repeat of early boundary violations that have left scars on the patient's psyche. One physician was charged with sexual misconduct by a patient who insisted that he had had "genital contact" with her. The physician adamantly denied it. When further inquiry was made, it became clear that during a hug the patient had experienced the pressure of the physician's genitals on her pelvis as "genital contact," reawakening old trauma.

There are, of course, cultural variations on the appropriateness of hugs or kisses. However, cultural differences can be used to rationalize behavior that patients perceive as offensive. Licensing boards frequently encounter physicians who claim that they are unfamiliar with American customs regarding touch. They may claim that within their culture, the kind of contact they had with the patient is entirely acceptable. A critical issue in these situations, of course, is that the patient may not be from the same culture and may feel extremely uncomfortable with the kind of contact initiated by the physician.

Beyond hugs or kisses, other forms of physical contacts may be viewed as a violation of the professional relationship. One woman reported that her gynecologist sensually rubbed her back while discussing the findings of her pelvic examination with her. Regardless of his intent, she perceived him as deriving sexual gratification from his contact with her.

PREVENTION OF BOUNDARY VIOLATIONS

The key to preventing boundary violations lies largely in education, although certain physicians whose characterological defects lead them to this behavior may not be deterred by such efforts. Medical students and residents should be taught the concept of professional conduct in conjunction with learning interviewing and physical diagnosis. Sensitivity to professional boundaries should be as routine as auscultating the chest. These issues should be discussed, not exclusively in the context of ethics courses, but in all clinically oriented courses. They are the fabric of the physician-patient relationship.

Information about the widespread prevalence of sexual abuse and its connection with subsequent revictimization also should be taught in medical school as part of this preventive education. It is well known that patients who have been sexually abused are at high risk for being sexually exploited by physicians and psychotherapists.[26,28,32] While we do not intend to blame patients for the boundary transgressions of their physicians, medical students need to be aware of the common dilemmas presented by sexually abused patients, particularly the rescue fantasies they inspire in physicians, who may gradually become overinvolved in an effort to repair the damage from the past.

Another area of education that would

be productive in the prevention of boundary violations is sensitivity to gender issues and gender differences. Professional conduct should take into account differences in the gender configuration of the physician-patient dyad and how that influences the perception of the physician and the content of the physician's communication. A corollary to this principle is the need to be empathic and nonjudgmental when taking into account differences related to sexual orientation and sexual preference.[21]

A crucial component of education is sensitivity to the diversity of the population and the associated cultural and individual differences, particularly regarding the meaning of touch and other forms of physical contact. What is therapeutic touch to one patient may be experienced as assaultive by another. Because the physician cannot know how a certain patient is likely to respond to various aspects of touch inherent in the physical examination, clear communication is of paramount importance. Physicians also must develop an empathic attunement to their patients so that they can sense the impact of any aspect of the examination that might be routine from their perspective but has special meaning to the patient. This attention to careful communication about examination procedures has enormous significance in a managed care era in which patients are routinely seeing new physicians with whom no sense of trust has developed. Similarly, following our previously mentioned guidelines for the presence of a chaperone may also be of particular value for new patients.

Role modeling cannot be overemphasized in medical education. The obverse of professional misconduct is, of course, professional conduct, which encompasses all the features of a humane physician-patient relationship as well as the sum total of professional boundaries. This overarching demeanor can best be learned by watching role models relate to their patients in the course of rounds, examinations, and other clinical settings. Teachers also must make it clear to their trainees that they are available as supervisors or consultants when students find themselves attracted to patients and are confused about how to manage such feelings.

In the midst of our enthusiasm for preventive education, we must also acknowledge that it is not a panacea. Some unscrupulous practitioners with severe personality disorders will be completely untouched by educational efforts. Their predatory behavior with patients is simply an extension of predatory behavior outside their professional lives.[2] The best we can hope for is that such individuals, who constitute a relatively small number of physicians, can be identified early in the medical school process and redirected toward other careers.

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Special Communication

The Role of Compulsiveness in the Normal Physician

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• This article presents some observations from a workshop setting about the role of compulsiveness in the normal physician. Case examples illustrate the effect of this character trait on the professional, personal, and family life of the typical physician. Doubt, guilt feelings, and an exaggerated sense of responsibility form a compulsive triad in the personality of the physician. This triad manifests itself in both adaptive and maladaptive ways. This article focuses primarily on the maladaptive, including difficulty in relaxing, reluctance to take vacations from work, problems in allocating time to family, an inappropriate and excessive sense of responsibility for things beyond one's control, chronic feelings of "not doing enough," difficulty setting limits, hypertrophied guilt feelings that interfere with the healthy pursuit of pleasure, and the confusion of selfishness with healthy self-interest.

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IN A prominent midwestern medical school, a professor of internal medicine exhorted a group of 100 eager first-year medical students in a course on physical diagnosis: "The most important quality of a physician," the professor stated grandly, "is compulsiveness." His audience of listeners compulsively wrote down every word he said, underlined every important phrase, and committed the entire text to memory. Although the professor's statement might be challenged by other medical educators, there is no doubt that compulsiveness is the hallmark of the physician's personality. In a poll of 100 randomly selected physicians, Krakowski[1] found that all 100 declared themselves to be "compulsive personalities." Eighty percent possessed three of the five criteria for the diagnosis given in the *Diagnostic and Statistical Manual of Mental Disorders*, edition 3, while 20% satisfied four of the five criteria, which include restricted ability to express warm and tender emotions, perfectionism, insistence that others submit to one's way of doing things, excessive devotion to work and productivity to the exclusion of pleasure and the value of interpersonal relationships, and indecisiveness. While it would be an exaggeration of the truth to declare that all physicians are diagnosable as having compulsive personality disorders, it is probably accurate to assert that compulsive *traits* are present in the majority of those individuals who seek out medicine as a profession. Hence, the normal physician may be described as a compulsive physician. Offer and Sabshin[2] have pointed out that normality is used in four general senses: normality as health, normality as average, normality as an ideal, and normality as process. In this context, I am using the concept of normality in the second sense, ie, as a statistical norm that describes the *typical* physician. Whether the normal compulsiveness of the physician is ideal or healthy is much less clear.

For the last several years, The Menninger Foundation has sponsored a series of workshops for physicians and their families at Estes Park, Colo. Those of us who have served on the faculty have had the opportunity to listen to hundreds of physicians describe remarkably similar problems that seem to grow out of their compulsive natures. While our sample is not truly scientific, since only those physicians interested in such a workshop are included, the observable trends and patterns are so consistent that they undoubtedly apply to many other physicians outside the sample. The intensive group experiences at those workshops have allowed us to gain a greater understanding of some of the underlying dynamics behind the problems created by compulsive character traits. This communication is an attempt to share some of these observations, without any implication

From the C. F. Menninger Memorial Hospital, The Menninger Foundation, the Karl Menninger School of Psychiatry, and the Topeka Institute for Psychoanalysis, Topeka, Kan.

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that such dynamics apply to all physicians or to any one particular physician.

TRIAD OF COMPULSIVENESS

Doubt, guilt feelings, and an exaggerated sense of responsibility seem to form a triad of compulsiveness that characterizes the physician's psychological makeup. Why do physicians have these compulsive traits? A certain type of personality is undoubtedly drawn to the profession of medicine.[3,4] Some studies[3,5] have shown that the physician may enter medicine as a way of dealing with an unconscious fear of death acquired during childhood. In their elegant controlled study of the psychological vulnerabilities of physicians, Vaillant et al[4] found that physicians are statistically more likely to manifest personality traits of dependency, pessimism, passivity, and self-doubt. Moreover, compulsive traits are not simply associated with persons in high-powered professional positions, since attorneys, for example, have been shown to be far less compulsive than physicians.[6]

On the other hand, whatever preexisting personality type may be attracted to the field of medicine, most would agree that the process of medical education itself enhances and positively reinforces whatever preexisting compulsiveness is present. There is some evidence[7,8] that the premedical curriculum, the medical school experience, and the stresses of residency foster the development of certain defense mechanisms that are typical of compulsive personalities. When it is not extreme to the point of being pathological, compulsiveness is a highly adaptive trait, which makes for diagnostic rigor. For example, doubt, the first element of the compulsive triad, leads the physician to "run the extra mile" and rule out the rare disease entity that a less conscientious person might fail to consider. It leads him to check and double-check laboratory data and physical findings for discrepancies and for minute changes that might be of significance. (The male pronoun is used here merely for convenience, for the compulsive traits are not gender specific and apply equally to the female physicians we have seen.) None of us would question the importance of thoroughness in the physician's diagnostic and therapeutic practice, and we would all probably choose a compulsive physician if we were seriously ill. Herein lies the grand paradox: compulsiveness and excessive conscientiousness are character traits that are socially valuable, but personally expensive. Society's meat is the physician's poison.

Doubt

If we examine the less adaptive aspects of doubt, the first element of the triad, we see that it may be a source of inner torment for the physician if he cannot be satisfied with the thoroughness of his diagnostic or therapeutic efforts. He may be obsessed with the notion that he has missed an important element in the clinical picture that will lead to the deterioration of the patient. If the patient should die, the physician may be overwhelmed with guilt feelings, the second component of the compulsiveness triad. He is certain that he has missed something along the way and that he is the one to blame for the death of his patient. No matter how thorough his diagnostic efforts, he is burdened with a profound sense of responsibility, the third element of the triad. A sense of responsibility *should* be inculcated in the physician throughout his education, and this sense becomes the source of pride and ethical conduct. However, when taken to the extreme view that whatever happens to one's patient is the physician's responsibility, the trait may verge on omnipotence. Just as the physician is often only peripherally involved in the patient's improvement, especially in such cases where nature takes its course, the physician may in no way be responsible for the death of his patient. The patient's own health habits may be at fault, an unexpected drug reaction may be responsible, or the hand of fate, ie, the natural course of events, may be the culprit. Nevertheless, the physician is likely to recall postmortem conferences where a self-assured and condescending pathologist pointed out to the participants exactly where the attending physician had erred in his assessment of the patient and how the patient's death could have been prevented.

Dr A, a 52-year-old family practitioner, agonized for years over the fact that 17 years ago he had "killed" one of his patients. He had given a young man penicillin for a bacterial pharyngitis, only to see the patient go into anaphylactic shock before his eyes and die. The physician recounted that office visit over and over again in his mind through a period of many years, as he ruminated over the exact exchange between himself and the patient, and his management of the allergic reaction. He repeatedly assured himself that the patient had denied any allergy to penicillin. He consulted a colleague about the situation and had lengthy discussions with the pathologist who performed the autopsy on the patient. They all attempted to reassure him that he was not responsible for the death of the patient. "It could have happened to anyone," they often told him. He spent over 50 hours poring over articles on anaphylactic shock and its treatment. For 17 years, he kept recalling that particular patient's name and still periodically lies awake at night going over the details of what happened.

Guilt

This case example demonstrates how the noble tradition of medical responsibility can lead to haunting and relentless guilt feelings. The emergence of overwhelming guilt feelings from incidents like this one is not simply the result of failure of the physician's defense against his own aggression, not simply his fantasy that his wish to harm others has been unchecked. It is also a reaction to a tremendous sense of inadequacy and helplessness. One of the determinants of the choice of the medical profession may be to defend against the horrible existential dread associated with feelings of impotence in the face of one's own ultimate death. In other words, physicians may pursue medicine to keep from feeling helpless as well as to keep from hurting others. Hence, there is often a secret omnipotence in the form of an overdeveloped expectation of one's self in the practice of medicine. The physician may harbor unconscious or conscious fantasies that he can outwrestle the Angel of Death. When he fails to do so, he is likely to blame himself for his shortcomings. The practice of medicine is, for the most part, only palliative; another grand paradox on which to reflect is that those individuals who are so vulnerable to feelings

of helplessness choose a profession where they are repeatedly reminded of their inherent impotence in the face of disease and death.

Exaggerated Sense of Responsibility

All of these concerns lead the physician to work exceedingly long hours. Overwork is often an attempt to clear his conscience by convincing himself and others that he has done everything he possibly could so that he could not be responsible for any deterioration of his patient.[9] His family, of course, are the recipients of the chaos caused by his later hours; the physician must deal with their disappointment at his arrival home at 8:30 PM and with his own guilt about disappointing them once again. Even though more and more physicians are shunning solo practice so they can have the shared-coverage arrangement of a group, the same difficulties persist. Many physicians still report a certain difficulty in turning over a patient to a colleague at 5 or 6 PM, when the physician's office hours are supposed to end so that he can go home.

Dr B, a 41-year-old family practitioner, was getting ready to leave his office at 6 PM to rush home and have supper before attending his son's final high school basketball game. The hospital called to inform him that one of his obstetric patients had arrived in labor and delivery and was currently showing 5 cm of cervical dilatation. He knew that one of his partners was covering obstetrics that night, but he felt compelled to run by the hospital to check her before going home. After checking her, he decided to stay through the delivery, necessitating his missing his son's last game. After the delivery, the physician sat in the locker room and wept. He felt terribly guilt-ridden over missing the game, and as he reflected on the evening, he could not understand why he had not simply handed the case over to his partner. He poignantly stated later that he was not even emotionally attached to this particular patient. His own narcissism had gotten the best of him, ie, he felt that *he* and *he alone* had to be the one to deliver the baby, as though his partner could not have performed exactly the same function.

This vignette is all too familiar to most of us. Many practitioners begin to feel pangs of anxiety if the clock rolls around to 5:30 or 6 PM, and they know that their spouses and children are waiting for them to get home and spend the evening with them. They feel torn between the guilt over leaving their patients in the office or the hospital, on the one hand, and the guilt over being late to see their families, on the other hand. As we all know, this quandary is usually solved in favor of the patient rather than the family. This phenomenon of overwork bears on another facet of the physician's psychological makeup, namely, his need to be needed. Just as the actor needs the applause of his audience for his emotional survival, so does the physician need to be loved, valued, and needed by his patients to maintain his psychological equilibrium. Children who grow up to be doctors seem to have a great deal of uncertainty about their value as individuals and their worth as lovable objects. Typically, they have been driven by the conviction that the road to parental approval is through the acceptance of more responsibility, more work, and more self-denial.

LEISURE TIME

Leisure time is another problem area for the compulsive physician. In Krakowski's sample of 100 physicians,[1] only 16 read for pleasure, attended theater or concerts, or viewed television as a pastime. Only ten regularly took time off to relax. A mere 11 took vacations exclusively for vacation's sake, while 15 combined them with attendance at professional meetings. Physicians are notorious in their difficulties with leisure time. In fact, Krakowski's study indicates that the general reaction to stress is to *increase* one's professional activity rather than to take time off and relax. The little leisure time that the physician does manage to work into his schedule is similarly guilt-ridden. There is always the temptation to use some of the time to pursue self-improvement, such as jogging or swimming, or to take time for the development of a hobby or interest. However, the physician often feels guilty about such activities because they mean time away from his family, and he is already consumed with guilt about the little time he has spent with his family. As one young family practitioner put it, "Time for work comes first; time for family is a distant second; and time for self is an even more distant third." Unstructured time may be the most anxiety-producing experience of all for the busy physician.

Dr C, a 38-year-old family practitioner in a group practice, looked forward during one particular week to a rare weekend with no call. He had no obligations or commitments to structure his time for the weekend. He found himself rather anxiously looking for guidelines, so he sat down and made a list of things he had to do during the weekend. He had a growing stack of unread journals, which he had to read to be fully up-to-date; the grass needed to be cut; the screen door needed to be repaired; the air conditioner in the car seemed to be malfunctioning. The list rapidly grew, and by Sunday evening he felt thoroughly frustrated with himself at not being able to accomplish all that he had set out to do. He reflected on how he had not only robbed himself of free time but had once again avoided any meaningful interaction with his family.

Such a physician is a driven person, who probably exemplifies the Protestant work ethic as much or more than members of any other profession. He feels guilty about leisure time. He may feel that he can only justify swimming or jogging if it is ultimately for the good of some other person. He can rationalize the fact that he takes time for jogging by convincing himself that he is preventing himself from having a heart attack, which would leave the family without financial support. Physicians have a terribly difficult time with goal-less play of any sort. The guilt over having free time may take many forms.

Dr D, a young cardiologist, had been ruminating for several months about taking a day off in the middle of the week to spend with his wife. When she finally managed to convince him that he should indeed take the time so they could shop for a new sofa together, the physician woke up on his day off with a sense of dread. He felt he was being sneaky and dishonest about being away from work. He was certain his colleagues must be grumbling about his absence. Before he could even get out the door to go shopping with his wife, he was struck with a migraine headache that forced him to go to bed for the rest of the day.

This dramatic example of somatization of the guilt feelings is not unusual. Some sort of punishment was required for this physician, who felt that he was guilty of a crime by staying home from work. Punish-

ments come in all different forms, but are built into the physician's lifestyle as though they are required for him to maintain homeostasis. Even the compulsive reading of the ubiquitous stack of journals is a form of punishment for some physicians. It is done in a dutiful way, as though the physician is making every possible effort to keep current with the literature. This effort is designed to ameliorate his anxiety over the fact that he never keep up with all that he needs to know. The current legal pressures involved in medical practice make this process even more guilt-ridden and more laden with anxiety about missing some important new development in the field. The threat of a malpractice suit has seriously eroded the traditional doctor-patient relationship and exponentially increased the physician's proneness to self-doubt and guilt feelings.

DENIAL

One of the core issues in the etiology of the physician's guilt seems to be his feeling that any effort on behalf of himself is selfish and in violation of a nonverbal contract for love that may have been made many years ago with his parents. This tacit agreement is understood by the physician to be the following: self-sacrifice is the way to be loved, while self-assertion is the road to alienation and separation from those sources of nurturance that are so fundamental. Because of this trouble in differentiating selfishness from healthy self-interest, the physician has difficulty dealing with his own aggression in the form of setting limits. He denies his own mortality, his own limitations, and his own human weaknesses by mounting an omnipotent campaign to defeat death and disease. This endeavor often leads to self-neglect, denial of his physical and emotional needs, and a self-destructive pattern of overwork.

COMMENT

Space considerations preclude a detailed discussion of strategies for dealing with the consequences of the compulsive tendencies enumerated above. Suffice it to say that ingrained behavior patterns are seldom easily altered. However, the first step toward a solution is the identification and recognition of the problem and its ramifications. It is my hope that the foregoing description of a particular character style and its behavioral manifestations in the life of the typical physician will strike chords of recognition in the physician reader and set him thinking about the consequences of these patterns in his own life.

The author is indebted to Roy W. Menninger, MD, for his helpful comments on this article.

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Newsline

Federation of State Medical Boards of the United States, Inc.

Fall 2013

New FSMB policy helps boards educate physicians on use of opioids for chronic pain

In July, the FSMB adopted a new *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain*, completing a comprehensive review of its longstanding *Model Policy for the Use of Controlled Substances for Pain*.

First developed in 1998 and revised in 2004, the updated FSMB policy is intended as a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances, while providing much-needed guidelines to help avoid the overtreatment or undertreatment of patients with pain.

> **"The *Model Policy* emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate."**
>
> –Excerpt from *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain*

Since the last revision of the *Model Policy* in 2004, a significant body of research and experience has accrued, providing new insights into the risks of opioid prescribing. In March 2012, the FSMB, in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA), brought together experts in pain management, pharmacology, psychiatry, public health, medical regulation and other disciplines to update the FSMB policy.

The workgroup examined new scientific research and public policy on opioids as a part of its review to ensure the policy was consistent with emerging medical insights regarding pain management and the use of controlled substances. The FSMB's new policy acknowledges that evidence for the risks associated with opioids has surged, while evidence for benefits of opioid use has remained controversial and insufficient. At the same time, however, it recognizes that chronic pain continues to be a major problem in the United States and that undertreatment of pain is a serious public health issue.

"It is incumbent upon the regulatory community to balance these two very clear realities as it seeks a sensible policy for the use of opioid analgesics in treating chronic pain," said Humayun Chaudhry, DO, FSMB's president and CEO. "The FSMB's new policy seeks to achieve this balance, reflecting a consensus of best practices among federal and state regulators as well as experts in addiction and pain medicine and other national stakeholders."

Significant revisions to the 2004 *Model Policy* include:

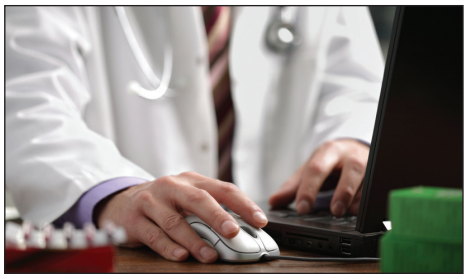
- Updated background information on the risks of prescribing;
- New measures for evaluation and screening aimed at helping reduce risk; and
- Guidelines to help ensure physicians who prescribe opioids do so in full compliance with state and federal regulations, accepted best clinical practices, and in a manner that is safe and reduces risk.

In addition to the *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain*, the FSMB adopted a related policy in April 2013 – the *Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office*. Together, these policies provide important guidance for clinicians as the medical community continues to face

...continued on page 2

Workgroup developing guidelines for evaluating standard of care for telemedicine

A new FSMB workgroup is reviewing existing policies on telemedicine with the goal of offering recommendations to state medical boards based on a thoughtful review of recent advances in



technology and the appropriate balance between enabling access to care while ensuring patient safety.

The FSMB State Medical Boards Appropriate Regulation of Telemedicine (SMART) Workgroup, which met in Washington, D.C., in August, includes state medical board representatives and experts in telehealth and telemedicine. The panel is charged with:

- Conducting a comprehensive literature review of telemedicine services and proposed/recommended standards of care;
- Identifying and evaluating existing telemedicine standards of care developed and implemented by state medical boards; and
- Revising the FSMB's 2002 policy, *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*

The workgroup will continue meeting via web-conference this fall to develop its draft report. It is anticipated that a draft report will be submitted to the FSMB Board of Directors in February 2014 and subsequently distributed to state medical boards and other stakeholders for comment before a final document is submitted for approval to the FSMB's House of Delegates in April 2014.

For more information, please contact Jonathan Jagoda, MPP, Director, FSMB Federal Policy and Government Relations, at jjagoda@fsmb.org.

New FSMB Model Policy – continued from page one

the twin challenges of treating chronic pain while confronting the public health threat of opioid misuse, abuse and addiction.

Both policies can be accessed in the Advocacy and Policy section of the FSMB website at www.fsmb.org. For more information, please contact Kelly Alfred, FSMB Director of Education, at kalfred@fsmb.org.

CME resources help physicians safely and effectively manage patients with chronic pain

The FSMB invites state medical boards to encourage their licensees to take advantage of several opportunities to help them learn how to safely and effectively manage patients with chronic pain while earning continuing medical education credits.

SCOPE of Pain program provides REMS training

The FDA has mandated that manufacturers of extended release/long-acting opioid analgesics, as part of a Risk Evaluation and Mitigation Strategy (REMS), make available comprehensive prescriber education in the safe use of these medications based on the FDA curriculum "Blueprint for Prescriber Education for Extended Release and Long-Acting Opioid (ER/LA) Analgesics."

Providers who prescribe extended release/long-acting opioid analgesics to treat chronic pain are in a key position to balance the benefits and risks of chronic opioid therapy. However, providers struggle with the need to assist their patients with adequate management of chronic pain while confronting the risks associated with opioid prescribing.

The FSMB, in collaboration with Boston University School of Medicine and the Council of Medical Specialty Societies, is co-sponsoring a program to provide this education, entitled *Safe and Competent Opioid Prescribing Education (SCOPE) of Pain*. A series of CME activities, SCOPE of Pain is designed to help licensees safely and effectively manage patients with chronic pain, when appropriate, with opioid analgesics.

SCOPE of Pain CME activities

- A three-module web-based activity is available at www.scopeofpain.com.
- Live conferences in 2013-14 will be held in these cities (registration is available at www.scopeofpain.com):
  - Oct. 25 – Raleigh, N.C.
  - Nov. 1 – Madison, Wisc.
  - Jan. 18 – San Rafael, Calif.
  - Feb. 22 – Columbia, S.C.

Revised *Responsible Opioid Prescribing* provides strategies for reducing risk of addiction

Newly revised and expanded, the FSMB Foundation's *Responsible Opioid Prescribing: A Clinician's Guide* translates best-practice guidelines from leading pain medicine societies and the FSMB into pragmatic steps for risk reduction and improved patient care.

Since its first release in 2007, *Responsible Opioid Prescribing* has been widely acknowledged and supported in the medical community as an important educational resource for physicians, and has been used extensively by state regulators and others to address the need for safer, more responsible and better-informed opioid prescribing.

Free CME available with *Responsible Opioid Prescribing*

Responsible Opioid Prescribing includes up to *7.25 AMA PRA Category 1 Credits*™ for free. More than 185,000 copies of the book have been purchased and distributed in recent years. Discounted bulk rates are available for medical boards interested in distributing the book to their licensees as an educational resource. For more information, visit www.fsmb.org or contact Kelly Alfred, FSMB Director of Education, at kalfred@fsmb.org.

Safer use of opioid analgesics

While opioid analgesics have an appropriate role in clinical care (see FSMB's *Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain* on page 1), they also have significant risks for patients and non-patients. To ensure their benefits continue to outweigh their risks, the federal Food and Drug Administration (FDA) has required a shared REMS for all extended-release (ER) and long-acting (LA) opioid analgesics *(ER/LA Opioid Analgesics REMS)*.[1]

The goal of the *ER/LA Opioid Analgesics REMS* is to reduce serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse of ER/LA opioid analgesics, while maintaining patient access to pain medications. Adverse outcomes of particular interest include addiction, unintentional overdose and death.

The FDA requires the consortium of companies with medicines subject to this REMS to jointly fund REMS-compliant Continuing Education (CE) activities, so prescribers can participate in them at nominal or no cost. The content of these CE activities is based on the FDA's "Blueprint"[2]. They are offered by CE providers who strictly adhere to the standards of the Accreditation Council for Continuing Medical Education (ACCME)

or other CE-accrediting bodies. REMS-compliant CE activities are currently available in live and online formats for physicians and other prescribers of opioid analgesics.

This REMS also includes a downloadable, one-page document, in English or Spanish, to facilitate counseling of patients and caregivers on the risks and safe use of these opioid analgesics at the time of prescribing.[3] Patients should also receive a Medication Guide from the

...continued on page 4

How medical boards benefit from using the Uniform Application

The FSMB's Uniform Application for Physician State Licensure (UA) is a web-based application designed to enhance the nation's state-based medical licensure system by simplifying and streamlining the process. The UA improves license portability by eliminating the need for physicians to reenter information when applying for licenses in multiple states. Physicians fill out the UA online once, and then use the application whenever they apply for licensure in another state that accepts or requires the UA – for the rest of their careers.

UA | UNIFORM APPLICATION FOR PHYSICIAN STATE LICENSURE

The core section of the Uniform Application contains data fields required by all boards, such as education, training, work experience, etc. A customized addendum allows each medical board to capture unique state-level requirements. Information provided by physicians is stored in a permanent data repository, which is available to physicians electronically if they decide to apply for licensure in another of the growing number of states using the Uniform Application.

How medical boards benefit from using the UA:

- **Boards can receive applicant data automatically via the UA web service**. The fully automatic UA web service allows applicant data to be submitted completely online and then deposited directly into a state medical board's database.

- **The UA can be integrated with existing state board licensing systems.** The application has successfully been implemented in a wide variety of state platforms. The FSMB has leveraged its relationships with large software vendors to develop standardized web service importers that can be used by all boards.

- **A growing number of states are using the UA.** Twenty states have implemented the Uniform Application and others are engaged at various levels of adopting the program. As more boards adopt the UA, physician application processing is expected to become more efficient and as a result, decrease processing delays. (For a complete list of states that are using the UA, please visit www.fsmb.org/ua.html.)

- **Grant funding can offset implementation costs.** The economic downturn in recent years has created operating budget restrictions for many medical boards – limiting their ability to upgrade to or implement often costly electronic licensure applications. To help offset implementation costs for boards, the FSMB has been awarded a license portability grant to potentially assist boards using the fully automatic UA web service version.

- **The UA links with the Federation Credentials Verification Service (FCVS) application form**. Approximately 70% of applicant data for the UA is pre-populated when the applicant uses FCVS. As UA usage continues to grow, the more than 165,000 FCVS users accessing this added convenience is expected to increase as well.

- **The UA can be utilized for MD, DO and resident licensure applications**. The service has been expanded to include physicians in training programs as well as those established in practice.

For more information:

Additional information about the UA is available at www.fsmb.org/ua.html or by contacting Ingo Hagemann, Director, Uniform Application, at ihagemann@fsmb.org or (817) 868-5030.

In the next *Journal of Medical Regulation*: State Medical Board Violence Survey

In the upcoming Fall 2013 issue of the FSMB's *Journal of Medical Regulation (JMR)*, the FSMB Foundation will present results from its recent survey, "Medical Board Exposure to Threats of Violence." The stressful conditions that often accompany state medical board investigations and disciplinary actions can create highly contentious and emotionally charged environments – which could be considered potential precursors to violence or violent threats. The survey seeks to ascertain the extent to which state medical board members and/or staff have experienced threats of violence and the actions taken by state boards in response to such threats. Each issue of the *JMR* is mailed to FSMB Fellows, Honorary Fellows and medical board staff; select articles are available for free at http://jmr.fsmb.org.

Save the Date for FSMB Board Attorneys Workshop

November 7-8, Portland, Oregon

Designed specifically for attorneys and legal staff of state medical boards, including individuals involved with the investigation and prosecution of physician licensure and disciplinary cases, the FSMB's Board Attorneys Workshop provides participants with the opportunity to share and exchange valuable information on case experiences, best practices and current issues pertinent to board attorneys.

For more information, visit www.fsmb.org.

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Safer use of opioid analgesics

–continued from page 2

pharmacy that contains safety information specific to the drug dispensed to them.

In the interest of safer use in clinical care and improved public health, FDA and the companies involved in this REMS strongly encourage all prescribers of opioid analgesics to complete a REMS-compliant CE program to update their knowledge of the safe use of these medicines.

A current list of REMS-compliant CE activities is available at a website maintained by the consortium (https://search.er-la-opioidrems.com/).

Editor's note: To enhance awareness of REMS-compliant CE, state medical boards are welcome to repurpose this article for their websites and newsletters to licensees.

[1] http://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm
[2] http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM277916.pdf
[3] http://www.er-la-opioidrems.com/lwgUI/rems/pcd.action

FSMB 102nd Annual Meeting
April 24-26, 2014, Denver, Colorado

The premier educational event for the medical regulatory community, the FSMB Annual Meeting addresses a wide range of subjects relevant to medical regulators. Drawing attendees from around the world, the Annual Meeting includes physicians and public representatives from state medical boards, board leadership and staff, influential federal and state government representatives, and leaders of U.S. and international medical organizations.

For more information about these and other FSMB events, visit www.fsmb.org.

Please send your questions, comments and article ideas to: Drew Carlson, ***FSMB Newsline,*** 400 Fuller Wiser Rd., Suite 300, Euless, TX, 76039, dcarlson@fsmb.org, (817) 868-4043. **Visit the FSMB's website at www.fsmb.org.**

Bill Text
113th Congress (2013-2014)
H.R.3077.IH

H.R.3077 -- TELE-MED Act of 2013 (Introduced in House - IH)

HR 3077 IH

113th CONGRESS

1st Session

H. R. 3077

To amend title XVIII of the Social Security Act to permit certain Medicare providers licensed in a State to provide telemedicine services to certain Medicare beneficiaries in a different State.

IN THE HOUSE OF REPRESENTATIVES

September 10, 2013

Mr. NUNES (for himself and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend title XVIII of the Social Security Act to permit certain Medicare providers licensed in a State to provide telemedicine services to certain Medicare beneficiaries in a different State.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the `TELEmedicine for MEDicare Act of 2013' or as the `TELE-MED Act of 2013'.

SEC. 2. PERMITTING CERTAIN MEDICARE PROVIDERS LICENSED IN A

STATE TO PROVIDE TELEMEDICINE SERVICES TO CERTAIN MEDICARE BENEFICIARIES IN A DIFFERENT STATE.

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

`SEC. 1899B. PERMITTING CERTAIN MEDICARE PROVIDERS LICENSED IN A STATE TO PROVIDE TELEMEDICINE SERVICES TO CERTAIN MEDICARE BENEFICIARIES IN A DIFFERENT STATE.

`(a) In General- In the case of a Medicare participating physician or practitioner who is licensed or otherwise legally authorized to provide a health care service in a State, such physician or practitioner may provide such a service as a telemedicine service to a Medicare beneficiary who is in a different State, and any requirement that such physician or practitioner obtain a comparable license or other comparable legal authorization from such different State with respect to the provision of such health care service by such physician or practitioner to such beneficiary shall not apply.

`(b) Enforcement- With respect to the provision of a service pursuant to this section, the licensing or authorizing State has jurisdiction to enforce the licensure or other legal authorization requirements of such primary State, including through disciplinary actions used by such State as of the day before the date of the enactment of this section.

`(c) Process To Establish Telemedicine Service Definition- Not later than 9 months after the date of the enactment of this section, the Secretary shall issue guidance to the States for developing a definition of the term `telemedicine services' for purposes of applying this section. For purposes of issuing such guidance, the Secretary shall solicit input from relevant stakeholders, including patients, health care providers, State government officials, health technology developers, insurers, employers, licensing boards, community health organizations, and other Federal agencies.

`(d) Report- Not later than 12 months after the date of the enactment of this section, the Secretary shall submit to Congress a report on the plans to develop and expand the use of current and emerging Internet and communications technologies to expand access of Medicare beneficiaries to health programs.

`(e) Definitions- For purposes of this section:

`(1) MEDICARE BENEFICIARY- The term `Medicare beneficiary' means an individual entitled to benefits under part A or enrolled under part B.

`(2) QUALIFYING PHYSICIAN OR PRACTITIONER- The term `Medicare participating physician or practitioner' means the following:

`(A) A physician (as defined in section 1861(r)) who is a participating physician or supplier (as defined in section 1842(h)(1)).

`(B) A practitioner (as defined in section 1842(b)(18)(C)) who is a participating physician or supplier (as defined in section 1842(h)(1)).

`(f) Construction- Nothing in this section may be construed to remove, limit, or otherwise affect any obligation of a covered health care professional under the Controlled Substances Act (21 U.S.C. 801 et seq.).'.

Federation of STATE MEDICAL BOARDS

Report of the Maintenance of Licensure Workgroup on Clinically Inactive Physicians

April 2013

Federation of STATE MEDICAL BOARDS

Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain

July 2013

The recommendations contained herein were adopted as policy by the Executive Committee of the Federation of State Medical Boards of the United States, Inc., July 2013.

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Federation of STATE MEDICAL BOARDS

MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

INTRODUCTION

The Federation of State Medical Boards (FSMB) is committed to assisting state Medical Boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. [1]. The FSMB updated its guidelines in 2003 [2] so that its Model Policy would reflect the best available evidence on management of pain and give adequate attention to both the undertreatment and overtreatment of pain and the inappropriate use of opioid analgesics.

Through these initiatives, the FSMB has sought to provide a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances while alleviating fears of regulatory scrutiny. The FSMB recognizes that inappropriate prescribing can contribute to adverse outcomes such as reduced function, opioid addiction, overdose, and death [3-5]. By promulgating its Model Policies, the FSMB has sought to provide a framework for the legitimate medical use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.

Since their publication, the 1998 and 2004 Model Policies have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted all or part of the Model Policies.[1]

The updated Model Policy presented here reflects the considerable body of research and experience accrued since the 2004 revision was adopted [2]. While recognizing that adequate evidence is currently lacking as to the effectiveness and safety of long-term opioid therapy, this Model Policy is designed to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

[1] As of March 7, 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

The FSMB encourages every state medical board to work with the state attorney general to evaluate the state's policies, regulations and laws in an effort to identify any barriers to the effective and appropriate use of opioids to relieve pain, while ensuring that adequate safeguards are in place to deter and rapidly detect those who would obtain opioid analgesics for nonmedical purposes [6-7].

The FSMB acknowledges with gratitude the efforts of the state board members and directors who collaborated to prepare this updated Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The FSMB also thanks SAMHSA for its support of this important project.

ISSUES ADDRESSED IN THE NEW MODEL POLICY

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated[8-10]. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living [4]. Pain arises from multiple causes and often is categorized as either *acute pain* (such as that from traumatic injury and surgery) or *chronic pain* (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy) [4,8]. This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients' functional status and quality of life [4,9]. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain [6,10-11].

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment [4,8,12]. Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB's last review [3]. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: (1) physician uncertainty or lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) physician misunderstanding of causes and manifestations of opioid dependence and addiction; (6) fear on the part of physicians of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse; (7) physicians practicing outside the bounds

of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate physician education about regulatory policies and processes [3-4,12,14-20]. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics [21-22]. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician's instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults [15]). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal [19-23].

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient's home. Therefore, the physician's duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed [18,23].

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets [19-21]. Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities [20-23,45].

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.

- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional

behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.

- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.

- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.

- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act [25] defines a "lawful prescription" as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

MODEL POLICY FOR THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

SECTION I: PREAMBLE

The (name of Board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The (name of Board) recognizes that principles of high-quality medical practice dictate that the people of the State of (name of state) have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41, 80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For

example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted

to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23]. With all patients, the physician's decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician's own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient's pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient's surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a "treatment contract") is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician's prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician's policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29]and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial

risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromotography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and "on the spot" changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of "false negatives and positives" [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of

treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

SECTION III: DEFINITIONS

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

The CSA does *not* limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in *Schedules II* or *III* under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD-10) of the World Health Organization [70], and the *Diagnostic and Statistical Manual* (*DSM*) of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of "substance dependence" meant addiction. In the upcoming DSM V, the term *dependence* is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term "substance use disorder" is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, "The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid" [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been "diverted" [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called *nonmedical use*) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms "opiate" and "opioid" interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. "Opioid" is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas "opiates" refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are "positive for opiates" have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are "negative for opiates" have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathologic process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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Federation of STATE MEDICAL BOARDS

REPORT OF THE MOL WORKGROUP ON CLINICALLY INACTIVE PHYSICIANS

EXECUTIVE SUMMARY

In summer 2011, then-FSMB Chair, Janelle Rhyne, MD, MACP, appointed the MOL Workgroup on Clinically Inactive Physicians to further explore and address clinically inactive physicians' participation in MOL. The Workgroup was charged to define the clinically inactive physician and develop pathway(s) that clinically inactive physicians may follow to successfully participate in MOL.

For the purposes of this report, the Workgroup defined the clinically inactive physician as one who is not engaged in direct, consultative or supervisory patient care at the time of licensure renewal, but who, as a result of their professional activities, influences the care provided by clinically active practitioners.

Given that the purpose of MOL is to advance professional development for all physicians, the MOL framework and process for clinically active and clinically inactive physicians should be similar (or equivalent) and should be grounded in the general competencies model. The Workgroup expects, however, that as clinically inactive physicians engage in this process, they will select different activities aimed at improving and evaluating their knowledge, skills and performance from those selected by clinically active physicians.

In order to assist state medical boards in implementing a process and system that will facilitate the participation of clinically inactive physicians in MOL, the Workgroup outlined responsibilities and guidelines for physicians, state boards and the FSMB. These are organized as follows:

Responsibilities and guidelines for physicians:

- Understand and engage in a process of practice-relevant lifelong learning based in the general competencies and utilizing the three MOL components.
- Participate in activities that reflect their day-to-day professional activities and maintain appropriate documentation of participation in such activities.
- Provide an accurate reflection of clinical status to the licensing authority for licensure purposes and to the specialty certification board for eligibility for MOC/OCC.

Responsibilities and guidelines for state medical boards:

- Define options for how physicians will comply with MOL, including how compliance will be verified
- Strive for consistency in the creation and execution of MOL programs.
- Undertake a readiness assessment when beginning an MOL program and incorporate questions about physicians' practices and daily professional activities and responsibilities as part of the license renewal application process in order to facilitate identification of clinically inactive physicians as well as those needing to participate in a reentry process.
- Implement a communication strategy to appropriately notify licensees of the requirements for MOL.

Responsibilities and guidelines for the FSMB:

- Advise and consult on MOL policies, procedures, recommendations, legislative activity and best practices.
- Consult and collaborate with and encourage appropriate organizations to identify and develop appropriate tools and activities.
- Encourage a pilot project(s) specifically directed at implementation of MOL for clinically inactive physicians.
- Monitor, periodically review the status of, and report on implementation of MOL for clinically inactive physicians to identify and share successes and best practices.
- Develop and disseminate modules or other education/communication tools explaining lifelong learning for use by state boards.
- Develop a separate communication strategy around the issue of clinically inactive physicians and their participation in MOL specifically.

BACKGROUND

In 2010, the Federation of State Medical Boards (FSMB) adopted as policy the following framework for Maintenance of Licensure (MOL):

As a condition of license renewal, physicians should provide evidence of participating in a program of professional development and lifelong learning that is based on the general competencies model:

- medical knowledge
- patient care
- interpersonal and communication skills
- practice based learning
- professionalism
- systems based practice

The following requirements reflect the three major components of what is known about effective lifelong learning in medicine.

1. **Reflective Self Assessment (What improvements can I make?)**
   Physicians must participate in an ongoing process of reflective self-evaluation, self-assessment and practice assessment, with subsequent successful completion of appropriate educational or improvement activities.
2. **Assessment of Knowledge and Skills (What do I need to know and be able to do?)**
   Physicians must demonstrate the knowledge, skills and abilities necessary to provide safe, effective patient care within the framework of the general competencies as they apply to their individual practice.
3. **Performance in Practice (How am I doing?)**
   Physicians must demonstrate accountability for performance in their practice using a variety of methods that incorporate reference data to assess their performance in practice and guide improvement.

The FSMB also adopted as policy a recommendation that physicians not in active clinical practice who wish to maintain an active license should be expected to comply with all Maintenance of Licensure requirements adopted by a state medical board. The issue of how clinically inactive physicians might participate in MOL was further addressed in the 2011 report of the FSMB MOL Implementation Group, which provided more detailed guidance to state boards regarding implementation of MOL programs. As part of its recommendations, the MOL Implementation Group recognized that clinically inactive physicians pose a unique challenge within MOL, noting that there is "little data about individual licensees and their types of practice and the nature of those practices." To address this issue, the MOL Implementation Group recommended that state boards begin collecting data about licensees' practice status and scope of practice as part of the license renewal process. This will be facilitated by adoption of the recommended data elements contained in the report of the FSMB Workgroup to Define a Minimal Data Set (Appendix A).

Charge to the MOL Workgroup on Clinically Inactive Physicians

In summer 2011, then-FSMB Chair, Janelle Rhyne, MD, MACP, appointed the MOL Workgroup on Clinically Inactive Physicians to further explore and address clinically inactive physicians' participation in MOL. The Workgroup was charged to define the clinically inactive physician and develop pathway(s) that clinically inactive physicians may follow to successfully participate in MOL.

Given the complexity of the issue and the desire to fully identify, review and discuss all relevant aspects of clinically inactive physicians' participation in MOL, the Workgroup spent the next 18 months addressing and completing its charge. The Workgroup used a deliberative process, including review of relevant information (e.g., state statutes regarding licensure of clinically inactive physicians, types of licenses issued by state boards, statutory and regulatory definitions of active clinical practice, definitions of clinically inactive physicians from other health care organizations) and interviews and discussions with subject matter experts regarding potential tools to facilitate clinically inactive physicians' participation in MOL (Appendix B).

Preamble

The recommendations of the MOL Workgroup on Clinically Inactive Physicians are intended to align with other MOL principles and policies that have been previously adopted by the FSMB, including the MOL Guiding Principles (Appendix C) and the recommendations of previous MOL workgroups. For the purposes of this report, the term "physicians" encompasses both MDs and DOs.

The purpose of MOL is to advance professional development; therefore, the professional development process for clinically active and clinically inactive physicians should be similar (or equivalent). While it is recognized that the knowledge, skills and performance that will be evaluated for clinically active physicians and clinically inactive physicians will differ, the general competencies (medical knowledge, patient care and procedural skills, interpersonal and communication skills, practice-based learning and improvement, professionalism, systems-based practice) should be incorporated as part of the MOL framework and process for all physicians.

Defining the clinically inactive physician

For the purposes of this report, the Workgroup defined the clinically *active* physician as one who, at the time of license renewal, is engaged in direct, consultative, or supervisory patient care, or as further defined by the states. The committee agreed that volunteer physicians, regardless of number of hours worked, provide direct, consultative, or supervisory patient care and, therefore, should comply with the same MOL standards as clinically active physicians.

The workgroup defined the clinically *inactive* physician as one who is not engaged in direct, consultative or supervisory patient care at the time of license renewal, but who, as a result of their professional activities, influences the care provided by clinically active practitioners. This definition is for the purposes of this report only; the workgroup acknowledges that state boards can and may have their own definitions and standards for what constitutes a clinically inactive physician. In the interest of license portability, however, similar definitions are encouraged. Examples of clinically inactive physicians include individuals with significant administrative responsibilities, for example, medical school deans, hospital and health plan medical officers, leadership of professional societies or health regulatory organizations, etc.

A clinically inactive physician who wants to reenter active clinical work should be required to go through a reentry process, as defined in the Report of the FSMB Special Committee on Reentry to Practice.[1]

Clinically inactive physicians who engage in some clinically active medical practice

The Workgroup 1) endorses the recommendation from the FSMB MOL Implementation Group that MOL should be relevant to the day-to-day activities of the individual physician; 2) acknowledges that the tools to assess and support continuous professional development for clinically inactive physicians are less developed at this

[1] FSMB. Report of the Special Committee on Reentry to Practice, April 2012. http://www.fsmb.org/pdf/pub-sp-cmt-reentry.pdf

point in time than tools that support continuous professional development for clinically active physicians; and 3) believes the ability to provide high-quality care will remain paramount. Therefore, the Workgroup expects that, as MOL is initially implemented, physicians whose primary job responsibilities are administrative in nature but who also engage in some clinical medical practice will elect to participate in MOL activities that focus on their clinical practice and care. As MOL implementation evolves over the next 10 years, however, it is expected that physicians who are primarily administratively focused will shift their MOL activities to reflect that focus. The MOL system will simultaneously ensure that physicians with solely a clinical focus will pursue sufficient continuous professional development in clinical realms to provide high-quality care.

Identification of clinically inactive physicians

As noted in the FSMB MOL Implementation Group report, clinically inactive physicians pose a unique challenge within MOL because little data is available to state boards about individual licensees and the nature/type of their practices. To ensure that physicians are engaging in MOL activities that are relevant to their practices and to their daily professional responsibilities, it will be important for state boards to be able to identify the practice profiles of their licensees. The Workgroup recommends adoption of the recommended data elements contained in the report of the FSMB Workgroup to Define a Minimal Data Set. Adoption and utilization of this data will be vital in identifying clinically inactive physicians and will facilitate identification of physicians' practice profiles and verification of appropriate participation in MOL.

Administrative licenses

The Workgroup does not recommend implementation or adoption of an administrative license category for clinically inactive physicians, particularly as a means to exempt clinically inactive physicians from participating in MOL. This recommendation stems from a recognition that many clinically inactive physicians desire to have a full, unrestricted license, either because of the issues of professional identity tied to having such a license or the requirement to have a full, unrestricted license for employment purposes. Additionally, an administrative license may be perceived as a restricted license by state boards and specialty boards, which may have a negative impact on a physician's ability to obtain licensure elsewhere and/or ability to maintain specialty board certification. Furthermore, some state boards have already had extensive discussions about whether to implement administrative license categories and have decided against utilizing them.

The Workgroup acknowledges, however, that some states already have an administrative license option and defers to states where they have existing language that deals with these issues. In all instances, however, MOL should allow clinically inactive physicians to maintain a license in keeping with existing practices used by the state board. In addition, in implementing MOL, state boards should, to the extent possible, utilize definitions already within their statutes and rules and regulations.

Regardless of the license type available to and sought by clinically inactive physicians, state boards ultimately should ensure safe and effective practice by all physicians. In addition, all license types/categories should be valued equally and should not discriminate against nor interfere with license portability for non-clinical physicians.

General Observations

The Workgroup made the following general observations about the participation of clinically inactive physicians in MOL:

1. Clinically inactive physicians engage in a wide spectrum of activities, many of which support other physicians performing direct patient care.

2. The three components of lifelong learning and the general competencies are the core of demonstrating MOL and can be used for clinically inactive physicians as well.
3. Continuing medical education (CME) is a valuable tool to facilitate clinically inactive physicians' compliance with MOL, when it is relevant to what the physician does in his or her daily professional responsibilities.

Recommendations

The Workgroup also made the following general recommendations for the development of systems and processes to facilitate the participation of clinically inactive physicians in MOL:

1. There is a need for parity of pathways in how clinically active and clinically inactive physicians participate in MOL. Specifically, while it is recognized that the activities clinically inactive physicians engage in for MOL may differ from those for clinically active physicians, clinically inactive physicians should be required to meet all three components of MOL. The Workgroup acknowledges that participation in MOL Component 3 may be challenging for clinically inactive physicians but recognizes that relevant organizations have and will develop tools to support participation. The guidelines for implementation of MOL for clinically active physicians as outlined in the report of the FSMB MOL Implementation Group should be followed (see Appendix D).
2. All licensed physicians should engage in self-assessment and improvement specific to their professional activities and identify any practice gaps in their own practice (e.g., measure, intervene, re-measure).
3. Participation in MOL should be optimally integrated into physicians' clinical and professional activities. Therefore, the tools and processes used for MOL should be flexible and broad enough to offer reasonable options to the spectrum of clinically inactive physicians. In addition, existing tools and activities that clinically inactive physicians utilize and are engaged in should enable them to comply with MOL requirements if such tools and activities attain appropriate quality standards.
4. Participation in the American Board of Medical Specialties' (ABMS) Maintenance of Certification (MOC) program or the American Osteopathic Association Bureau of Osteopathic Specialists (AOA BOS) Osteopathic Continuous Certification (OCC) program should allow both clinically active and clinically inactive physicians to substantially comply with MOL.
5. There should be consistency in the auditing processes used for clinically active and clinically inactive physicians. Clinically inactive physicians should be subject to audit as part of the license renewal process at the same rates as other physicians.
6. The options and processes for MOL for clinically inactive physicians should balance transparency with privacy protection.
7. State boards should have a communication strategy in place to inform clinically inactive physicians of the requirements for MOL.

General Competencies

The general competencies (medical knowledge, patient care and procedural skills, interpersonal and communication skills, practice-based learning and improvement, professionalism, systems-based practice) adopted across the continuum of medical education and training should be incorporated as part of the MOL framework and process for physicians.

These competencies can be broadly defined within the context of both clinical and non-clinical medical settings and help maintain parallel standards between clinically inactive physicians and clinically active physicians for purposes of MOL. Types of activities clinically inactive physicians might engage in or utilize to meet a state's MOL

requirements and to demonstrate utilization of the general competencies are discussed below. These examples are provided as guidance only and not meant to be inclusive or prescriptive.

- A physician administrator may have improvement plans in place and be engaged in ongoing development activities. The state board would not look at outcomes or specific data, but would rely on attestation that the physician engaged in appropriate activities.
- A medical school dean might be required to demonstrate that he/she has participated in an accreditation process that measured outcomes (e.g., using Liaison Committee on Medical Education self-study).
- A public health/community physician might evaluate improvement in vaccination rates, epidemiologic tracers done during outbreaks, improvements in water systems, zoonosis tracers, etc.
- A health plan Chief Medical Officer (CMO) might evaluate aggregate patient experience of care results for a site or specialty group before and after an intervention on clinical staff education, or focusing on simplifying system-related complications in getting prescriptions filled. Community to hospital times, or door to balloon/bypass surgery times for patients with acute coronary events could also be evaluated. A last example might focus on the credentialing process with outcomes being the number of physicians who completed 360 evaluations, met institutional targets for decreasing re-admissions or are participating in MOC/OCC.

MOL Component 3 activities match with activities already being done in hospitals, managed care organizations, and other institutions.

Responsibilities/Guidelines for Physicians

The following guidelines are intended to define physicians' responsibilities within a MOL system:

1. Understand lifelong learning and how it works, as well as the general competencies.
2. Engage in a lifelong learning and quality improvement process utilizing the three MOL components.
3. Provide an accurate reflection of his/her clinical status to his/her licensing authority for licensure purposes and to his/her specialty certification board for eligibility for MOC/OCC.
4. Engage in appropriate activities for MOL (e.g., those that have been "approved" by the state board as appropriate for MOL) and maintain records of engagement in such activities.
5. When determining and selecting activities to engage in for MOL, choose those that reflect their day-to-day professional activities.
6. Keep records of attestations and any data needed for the purpose of audits conducted as part of the license renewal process. Physicians are already required to maintain records of CME; policies around retention of records and data for MOL should be similar.

Responsibilities/Guidelines for State Medical Boards

The following guidelines are intended to define state boards' responsibilities within a MOL system:

1. Define options for how physicians will comply with MOL. Specifically, the state board should review current requirements for license renewal (for most state boards, this will just be CME), decide whether they are appropriate for clinically inactive physicians, and define additional options. When evaluating options and tools beyond CME and MOC/OCC, the state board should take into account the cost and availability of options, avoid options that are onerous for either physicians or state board staff and attempt to include options that would be performed by the physician in

other venues. As stated in prior FSMB MOL reports, a high-stakes exam (summative assessment) is not required for purposes of MOL, and should not be required for clinically inactive physicians. However, examinations should be an option available to all physicians to comply with MOL. In addition, MOL is a low-stakes process which focuses on formative assessment, not summative assessment; therefore, other activities and evaluation tools are more appropriate.

2. Determine how physicians' participation in activities will be verified. The state board should specifically decide whether it will audit some percentage of licensees as part of the license renewal process and, if so, if attestations of participation in relevant activities can be used and how to confirm adequate completion of options without breaching confidentiality and HIPAA issues. The workgroup anticipates this process will be similar to processes currently used to verify compliance with CME requirements and will be subject to the development of pilot projects.
3. Adopt and implement the guidelines set forth in the Report of the FSMB Workgroup to Define a Minimal Data Set to obtain estimates of numbers for reentry and clinically inactive physicians.
4. If a clinically inactive physician wants to reenter active clinical work, the state boards should require him/her to go through a reentry process, as defined in the Report of the FSMB Special Committee on Reentry to Practice.
5. Develop and implement a communication strategy to appropriately notify physicians of the requirements for MOL. As previously noted in the report of the FSMB MOL Advisory Group, the communication strategy should also ensure that all licensees (both current and future), the public, and all other relevant stakeholders and interested parties (e.g., state societies, specialty societies, malpractice insurers, payers, hospitals) understand the importance of lifelong learning and continuous professional development and how participation in such activities can result in improved outcomes for patients and the health care system.
6. As previously recommended in the FSMB MOL Implementation Group report, state boards may want to undertake a readiness assessment when they begin an MOL program within their jurisdiction (see Appendix E for specific recommendations from the FSMB MOL Implementation Group).
7. As recommended in the FSMB MOL Implementation Group report, state boards should strive for consistency in the process and periodicity of MOL programs. While there is a need for guidelines that are flexible to meet state-specific criteria and regulations that are already in place regarding clinically inactive physicians, physicians may be concerned about an overly complicated process where they might have to meet varying criteria to maintain licensure in different states. The FSMB should assist state boards in coordinating the implementation of MOL so there is as much consistency as possible in order to facilitate license portability.

Responsibilities/Guidelines for FSMB

The following recommendations are provided to facilitate FSMB's continued collaboration with its member boards regarding implementation of MOL for clinically inactive physicians:

1. Advise and consult on MOL policies, procedures, recommendations, legislative activity and best practices.
2. Consult and collaborate with appropriate organizations to identify appropriate tools; encourage other organizations and medical specialty societies to develop additional tools and activities. Tools should meet all of the following criteria, as recommended in the report of the FSMB MOL Implementation Group: 1) be developed by an objective third party with demonstrated expertise in these activities; 2) be structured, validated, and reproducible; 3) be credible with the public and profession; 4) provide meaningful assessment feedback to the licensee appropriate to the scope of the activity to guide subsequent education; and 5) provide formal documentation that describes both

the nature of the activity (i.e., content and areas assessed) and successful completion of the activity as designed.[2]

3. Encourage a pilot project(s) specifically directed at implementation of MOL for clinically inactive physicians.
4. Monitor implementation of MOL to identify and share successes and best practices.
5. Periodically review the status of implementation of MOL for clinically inactive physicians and report back to the FSMB Board of Directors. Review and revise policies as needed.
6. Develop and disseminate modules or other education/communication tools explaining lifelong learning for use by state boards; such modules could be posted on state boards' websites or in relevant publications.
7. Develop a separate communication strategy around the issue of clinically inactive physicians and their participation in MOL specifically.

Conclusion

The general intent of MOL is to facilitate physicians' participation in lifelong learning and continuous professional development activities that will lead to improved patient care and outcomes. As such, the integration of clinically inactive physicians into the MOL process poses unique challenges to state boards, due in part to the extensive variety in their professional roles and responsibilities. However, even though clinically inactive physicians do not engage in direct patient care, their daily professional responsibilities ultimately have an impact on the quality of patient care provided by clinically active physicians. Therefore, clinically inactive physicians who wish to maintain an active license should be required to participate in all three components of MOL; there should not be separate processes or standards for MOL between clinically active and clinically inactive physicians, nor should clinically inactive physicians be exempt from any component of MOL.

To facilitate clinically inactive physicians' participation in MOL, state boards should begin collecting information about licensees' daily professional responsibilities to enable them to identify clinically inactive physicians, and FSMB should collaborate with state boards to develop appropriate communication and education pieces about clinically inactive physicians, the value they add to the health care system, and how they can participate in MOL. The FSMB should also consult and collaborate with other external stakeholders to expand the type and availability of tools and activities to support clinically inactive physicians' participation in MOL.

[2] FSMB. Report of the MOL Implementation Group, 2011. http://www.fsmb.org/pdf/BD_RPT_1103_%20MOL.pdf

APPENDIX A

Recommended Data Elements from the Report of the FSMB Workgroup to Define a Minimal Data Set: Report on a Recommended Framework for a Minimal Physician Data Set (2012)

RECOMMENDED DATA ELEMENTS FOR A MINIMAL PHYSICIAN DATA SET

The MDS Workgroup identified the data elements listed below to be included in a uniform, minimal physician data set. The workgroup believes that many of the elements indentified fall into one of three categories: (1) data currently provided by state boards as part of their regular transmissions of licensure data; (2) data that is or may be obtained by the FSMB through data sharing agreements with other organizations; or (3) unique and standardized data that state boards can obtain by adding questions to their renewal application or by asking questions as part of a separate questionnaire tied directly to the renewal process.

Data Element	Source and Rationale (when applicable)
Licensure status (active or inactive)	Currently provided by state boards.
Date of birth (mm/dd/yy)	Currently provided by state boards. FSMB has the date of birth for more than 96% of physicians with an active license.
Medical school graduated	Currently provided by state boards. FSMB has medical school matriculation data for more than 99% of physicians with an active license.
Medical school graduation year	Currently provided by state boards. FSMB has the medical school graduation year for more than 98% of physicians with an active license.
Specialty and subspecialty board certification	Obtained by FSMB. Specialty and subspecialty certification data is currently provided to FSMB by ABMS on a daily basis. FSMB is working with AOA to obtain access to their specialty and subspecialty certification data.
Maintenance of Certification and Osteopathic Continuous Certification	Obtained by FSMB from the ABMS and the AOA as the information becomes available.
Maintenance of Licensure	Provided by state boards as MOL programs are adopted and implemented.
Employment status	State board question. Physicians may hold an active license but be retired.
Provide clinical or patient care.	State board question. Physician may hold a position in a field of medicine, but do not provide direct patient care (important for reentry decisions by state boards).
If no, number of years since provided clinical or patient care	State board question. Provides important input for physician re-entry.
Areas of practice	State board question. This question provides input on the true areas of practice for a physician (primary care, dermatology, surgery).
Practice settings	State board question. Physician can practice in different settings (e.g., clinic or hospital).
Number of weeks worked during the past year	State board question. This information will help state boards better understand the level of participation among licensed physicians in their jurisdictions.
Average number of hours worked per week by activity	State board question. Some physicians are involved in direct patient care and work as an administrator and conduct research during the same week.
Clinical locations	State board question. Some physicians may work in more than one location.
Hours per week providing patient care by location	State board question. Some physicians may work varying amounts in more than one location.
Gender	State board question. FSMB to supplement with AAMC, AACOM, and ECFMG data.
Race (optional)	State board question. FSMB to supplement with AAMC, AACOM, and ECFMG data.

Data Element	Source and Rationale (when applicable)
Ethnicity (optional)	State board question. FSMB to supplement with AAMC, AACOM, and ECFMG data.
Languages spoken (optional)	State board question.

Federation of State Medical Boards. Workgroup to Define a Minimal Data Set: Report on a Recommended Framework for a Minimal Physician Data Set, April 2012. Available at: http://www.fsmb.org/pdf/grpol-min-phy-dataset.pdf

APPENDIX B

Advisors

The MOL Workgroup on Clinically Inactive Physicians consulted with the following individuals and organizations regarding potential tools to facilitate clinically inactive physicians' participation in MOL. The Workgroup expresses their gratitude to them for their assistance.

- Peter Angood, MD, FRCS(C), FACS, FCCM (American College of Physician Executives)
- Ronald Ayres, DO, and Cheryl Gross (AOA Bureau of Osteopathic Specialists)
- John Combes, MD (American Hospital Association)
- Norman Kahn, Jr., MD (Council of Medical Specialty Societies)
- Murray Kopelow, MD, MS(Comm), FRCPC (Accreditation Council for Continuing Medical Education)
- Richard Siegrist, MS, MBA, CPA (Harvard School of Public Health)

APPENDIX C

MOL Guiding Principles
(Adopted 2008, revised 2010)

- Maintenance of licensure should support physicians' commitment to lifelong learning and facilitate improvement in physician practice.

- Maintenance of licensure systems should be administratively feasible and should be developed in collaboration with other stakeholders. The authority for establishing maintenance of licensure requirements should remain within the purview of state medical boards.

- Maintenance of licensure should not compromise patient care or create barriers to physician practice.

- The infrastructure to support physician compliance with maintenance of licensure requirements must be flexible and offer a choice of options for meeting requirements.

- Maintenance of licensure processes should balance transparency with privacy protections.

APPENDIX D

Key MOL Recommendations from the Report of the FSMB MOL Implementation Group (2011)

1. MOL Component 1: State member boards should require each licensee to complete certified and/or accredited Continuing Medical Education (CME), a majority of which is practice-relevant and supports performance improvement.

2. MOL Component 2: State member boards should require licensees to undertake objective knowledge and skills assessments to identify learning opportunities and guide improvement activities. Component Two activities should meet all of the following criteria:

   a. be developed by an objective third-party with demonstrated expertise in these activities;
   b. be structured, validated and reproducible;
   c. be credible with the public and profession;
   d. provide meaningful assessment feedback to the licensee appropriate to the scope of the activity to guide subsequent education; and
   e. provide formal documentation that describes both the nature of the activity (i.e., content and areas assessed) and successful completion of the activity as designed.

3. MOL Component 3: State member boards should require licensees to use comparative data and, when available, evolving performance expectations to assess the quality of care they provide and then apply best evidence or consensus recommendations to improve and subsequently reassess their care.

4. Periodicity: State member boards should require each licensee to complete a minimum Component One activity on an annualized basis, a majority of which is devoted to practice-relevant CME that supports performance improvement; and to document completion of both one Component Two and one Component Three activity every five to six years.

5. Board Certification in the Context of MOL: SMBs should consider physicians who provide evidence of successful ongoing participation in ABMS Maintenance of Certification (MOC) or AOA BOS Osteopathic Continuous Certification (OCC) to have fulfilled all three components of MOL.

6. Need for More Information about Physician Practices: State member boards should regularly collect data from individual licensees about the extent of their engagement in direct patient care and the nature of their daily professional work.

Federation of State Medical Boards. Report of the MOL Implementation Group, 2011. Available at: http://www.fsmb.org/pdf/BD_RPT_1103_%20MOL.pdf

APPENDIX E

Key Components of a State Medical Board Readiness Assessment from the Report of the FSMB MOL Implementation Group (2011)

1. Communicate with licensees, training programs and medical schools about the MOL changes, available support resources and suggested preparations;

2. Review their medical practice act, policies, rules and regulations to identify any modifications required to enable the state medical board to implement MOL in the short and longer term, such as the need to define or redefine "clinically inactive"; anticipate any legal or legislative opportunities or challenges;

3. Take inventory of state medical board financial and staff resources and make any changes possible to align them with the final scope and design of the state medical board's MOL program;

4. Evaluate data needs and determine if additional physician demographic and practice data will be collected at the state level or secured from a third party repository (as available);

5. Make concrete decisions on program design and determine which activities will be deemed approved by the state medical board as meeting MOL requirements;

6. Determine the manner of verification of licensee participation in each component of MOL (e.g. physician attestation with verifying audit of a defined percentage of licensees each license cycle, electronic/automated reporting of compliance with certain elements, 3rd party attestation, etc.);

7. Meet with legislators, state medical and osteopathic societies, the physician community, the public and other key stakeholders to explain MOL changes and to discuss the impact of MOL on physicians and the public;

8. Revise the license renewal application as needed to collect information about licensees' scope of practice and practice status; and

9. Evaluate "types" of licenses available and whether additional license categories need to be created to accommodate licensees' expected participation in MOL. As part of this evaluation, state medical boards are encouraged to consider, in particular, licensees not involved in direct patient care, including any fiscal or other impact to the state medical board.

Federation of State Medical Boards. Report of the MOL Implementation Group, 2011. Available at: http://www.fsmb.org/pdf/BD_RPT_1103_%20MOL.pdf

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Robert A. Crittenden, MD, MPH

Senior Health Policy Advisor to the Governor

Rober Crittenden, MD has practiced as a family physician for over 28 years in Central and Southeast Seattle with urban underserved populations, worked for the state legislature, been a Robert Wood Johnson Health Policy Fellow with Senator George Mitchell, was special assistant to Governor Gardner for health, and is a Professor in the Departments of Family Medicine and Health Services at the University of Washington. He has been involved in many local and national efforts to improve the health care system including insurance improvements, being Associate Executive Director of the commission that put together the Basic Health Plan, a Board member of both the PEBB and the Washington State Health Insurance Pool. He has initiated the Kids Get Care program, has been active in rural and urban underserved health systems improvements, and has worked with insurers, employers and providers in improving systems of care for chronic conditions. Previously, he was the Chief of Family Medicine Service at Harborview Medical Center, on the boards of Families USA Foundation, Northwest Health Law Advocates, National Academy of State Health Policy, Immediate Past President of the Rainier Institute, and convener of the Working for Health and the Communities Connect Coalitions in Washington State. He is working on projects at the local, state and national levels focusing on improving the access and effectiveness of health services for all populations.

Dr. Crittenden received his BA in Communications and Public Policy from the University of California, Berkeley and a diploma in Political Theory and Development Economics from the University of Oxford. He went on to earn his Medical Degree at the University of Washington School of Medicine and his Masters of Public Health in Health Services from the University of Washington. He loves any sport and enjoys his time on the lake or in the mountains.

Scott M. Fishman, MD

Chief, Division of Pain Medicine
Professor of Anesthesiology and Pain Medicine
University of California, Davis

Scott M. Fishman, MD, is Professor, Chief of the Division of Pain Medicine, and Vice Chair for Pain Medicine and Faculty Development in the Department of Anesthesiology and Pain Medicine at the University of California, Davis. He was formerly Medical Director of the Massachusetts General Hospital Pain Center at Harvard Medical School. His medical degree is from the University of Massachusetts Medical School and his formal clinical training is in Internal Medicine (Greenwich/Yale University School of Medicine) and Psychiatry (Massachusetts General/Harvard Medical School). He completed Pain Medicine fellowship training through the Department of Anesthesia and Critical Care at Massachusetts General Hospital. Dr. Fishman has received board certification in Internal Medicine, Psychiatry, Pain Medicine, and Palliative Medicine.

Dr. Fishman lectures on all aspects of pain and its treatment throughout the U.S. He has authored *The War on Pain* through Harper Collins Publishers and *Listening to Pain* through Waterford Life Sciences. He has also co-authored *The Massachusetts General Hospital Handbook of Pain Management*, 2nd edition (Lippincott), *Essentials of Pain Medicine and Regional Anesthesia* (Elsevier), *Spinal Cord Stimulation: Implantation Techniques* (Oxford Univ. Press), and the forthcoming Bonica's *Management of Pain*, 4th edition(Lippincott). He has recently authored *Responsible Opioid Prescribing* for the Federation of State Medical Boards which will be delivered to U.S. prescribers through state medical boards. Dr. Fishman has authored many peer-reviewed articles in medical journals, book chapters, and other scholarly reviews. He is senior editor of the journal *Pain Medicine* and serves on the editorial boards of other medical journals.

Dr. Fishman is President and Chairman of the Board for the American Pain Foundation. He is past president of the American Academy of Pain Medicine and previously served on the board of directors for the American Pain Society. He advocates for the field of pain medicine with consumers and lawmakers, having testified in both state and national legislatures. He serves as a consultant to numerous government agencies and organizations such as the Federation of State Medical Boards, The Drug Enforcement Agency (DEA), The Department of Health and Human Services, state medical boards, and other regulatory agencies.

Dr. Fishman has appeared widely in major TV media such as the *Today Show, Good Morning America*, and the *ABC Nightly News* and has been quoted in the major written press such as *The New York Times, Wall Street Journal, Time Magazine, and Newsweek*. He has served as the Pain Expert for Discoveryhealth.com and has a monthly question and answer column for the American Pain Foundation

newsletter. Dr. Fishman has most recently been honored with the University of California, Davis Dean's Award for Excellence in Mentoring, the John and Emma Bonica Award for Public Service from the American Pain Society, the American Academy of Pain Medicine/Phillip Lippe Award for Outstanding Contributions to the Social and Political Aspect of Pain Medicine, Ambassador of the Year by the National Pain Foundation, The Head & Heart Award from the American Academy of Pain Management, and the Josephina Magno Award for Excellence in Education and Leadership from the Capital Hospice in Washington, DC.

Glen O. Gabbard, MD

Clinical Professor of Psychiatry, the Gabbard Center

Dr. Glen Gabbard is a professor of Psychiatry at SUNY Upstate Medical University in Syracuse, New York; Clinical Professor of Psychiatry at Baylor College of Medicine in Houston; and Training and Supervising Analyst at the Center for Psychoanalytic Studies in Houston. He is in private practice at the Gabbard Center located in Houston.

Dr. Gabbard attended Northwestern University and the University of Texas, and earned his Bachelor's Degree in Theater from Eastern Illinois University. He then earned his M.D. from Rush Medical College in Chicago in 1975. He completed his psychiatry residency at the Karl Menninger School of Psychiatry in Topeka, Kansas. He then served on the staff of the Menninger Clinic for 26 years and served as Director of the Menninger Hospital from 1989 to 1994 and Director of the Topeka Institute for Psychoanalysis from 1996 to 2001. In 2001, he moved to Baylor College of Medicine, where he served as Professor of Psychiatry and Brown Foundation Chair of Psychoanalysis until 2011.

Gabbard has authored or edited 27 books and over 320 papers, including books on professional boundary violations, physician health, and media depictions of psychiatry and mental illness in films with his brother Krin. He was Joint Editor-in-Chief of the *International Journal of Psychoanalysis* and was Associate Editor of the *American Journal of Psychiatry*.

Awards include the Strecker Award for outstanding psychiatrist under age 50 in 1994, the Sigourney Award for Outstanding Contributions to Psychoanalysis in 2000, the American Psychiatric Association Distinguished Service Award in 2002, the American Psychiatric Association Adolf Meyer Award in 2004, and the Rush Medical College Distinguished Alumnus in 2005. In 2010 he received the American Psychiatric Association/National Institute of Mental Health Vestermark Award as outstanding psychiatric educator.

Selected Publications

- Gabbard GO, Wilkinson SM (1994). *Management of Countertransference with Borderline Patients*. American Psychiatric Press
- Gabbard GO (2002). *The Psychology of the Sopranos: Love, Death, Desire and Betrayal in America's Favorite Gangster Family*. Basic Books ISBN 978-0-465-02735-4
- Gabbard GO, Lester EP (2002). *Boundaries and Boundary Violations in Psychoanalysis*. New York: Basic Books
- Gabbard GO (2005). Mind, brain, and personality disorders. *American Journal of Psychiatry* 162(4): 648-655
- Gabbard GO (2007). *Gabbard's Treatments of Psychiatric Disorders*. American Psychiatric Press. ISBN 978-1-58562-216-0

Thomas H. Gallagher, MD

Professor, UW School of Medicine

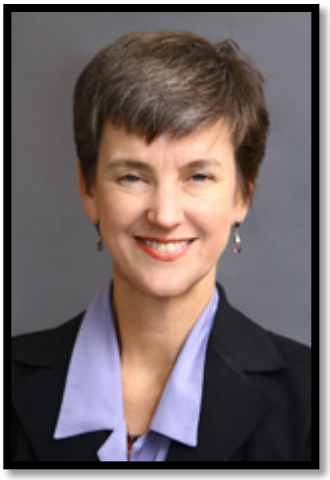
Thomas H. Gallagher, M.D., is a general internist who is a Professor in the Department of Medicine and the Department of Bioethics and Humanities at the University of Washington. Dr. Gallagher received his medical degree from Harvard University, Cambridge, Massachusetts, completed his residency in Internal Medicine at Barnes Hospital, Washington University, St. Louis, and completed a fellowship in the Robert Wood Johnson Clinical Scholars Program, UCSF.

Dr. Gallagher's research addresses the interfaces between healthcare quality, communication, and transparency. Dr. Gallagher has published over 70 articles and book chapters on patient safety and error disclosure, which have appeared in leading journals including *JAMA, New England Journal of Medicine, Health Affairs, Surgery, Journal of Clinical Oncology, Archives of Internal Medicine, Archives of Pediatric and Adolescent Medicine, and the Joint Commission Journal.* His work in error disclosure received the 2004 Best Published Research Paper of the Year award from the Society of General Internal Medicine, as well as the 2012 MITSS Hope Award. He also received a Robert Wood Johnson Foundation Investigator Award in Health Policy Research. He is the principal investigator on two grants from the Agency for Healthcare Research and Quality, including an AHRQ patient safety and medical liability demonstration project entitled "Communication to Prevent and Respond to Medical Injuries: WA State Collaborative." He also is principal investigator on grants from the National Cancer Institute, the Robert Wood Johnson Foundation, and the Greenwall Foundation. He is senior author of the book *Talking with Patients and Families About Medical Errors: A Guide for Education and Practice*, published in 2011 by The Johns Hopkins University Press. At the University of Washington, he directs the UW Medicine Center for Scholarship in Patient Care Quality and Safety, and also directs the UW Program in Hospital Medicine. He is an appointed Commissioner on the National Commission on Physician Payment Reform.

Dr. Gallagher is an active member of many professional organizations, including the American College of Physicians (Fellow) and the American Society of Bioethics and Humanities. He was recently elected to the Council (Board of Directors) for the Society of General Internal Medicine.

Ann C. Greiner

Vice President of External Affairs, National Quality Forum



Ann Greiner is vice president of external affairs at the National Quality Forum (NQF), a nonprofit membership organization created to develop and implement a national strategy for healthcare quality measurement and reporting. Ms. Greiner has more than 17 years of experience in leadership positions in health policy, research, and communications.

Before joining NQF, Ms. Greiner was vice president of policy for the American Board of Internal Medicine (ABIM). At ABIM, she helped establish the specialty certifying boards in the federal policy arena, resulting in their inclusion in the federal accountability framework established by the Affordable Care Act. Before ABIM, Ms. Greiner was deputy director of the Board on Health Care Services at the Institute of Medicine, where she edited three reports in the Quality Chasm series and organized two national summits.

Ms. Greiner began her career in healthcare quality at the National Committee for Quality Assurance (NCQA), where she led the rollout of the first national quality reporting efforts for healthcare focused on HMOs. She has consulted widely over her career, including consultancies with the Institute for Healthcare Improvement, Harvard University, and NQF.

Ms. Greiner is an alumna of Hobart and William Smith and received her master's degree at the Massachusetts Institute of Technology.

Gabrielle S. Hobday, MD, MA

Forensic Psychiatrist, the Gabbard Center

Gabrielle S. Hobday, MD is a forensic psychiatrist at The Gabbard Center in Bellaire, Texas, where she does three-day outpatient professional assessments on physicians and other professionals who are sent by licensing boards, physician health programs and hospitals. She is also a Clinical Assistant Professor of Psychiatry at Baylor College of Medicine in Houston, where she teaches psychotherapy to residents. Previously, she served as Assistant Director for forensic evaluations at the Baylor Psychiatry Clinic in Houston.

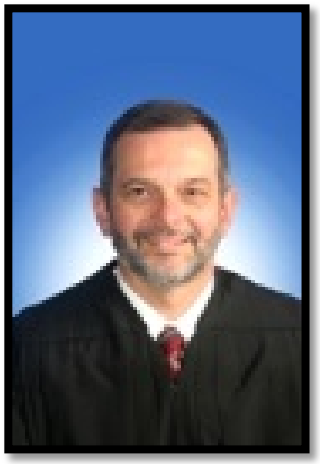
In her forensic work she reviews records and can be called to testify on issues related to ethics, professionalism, and boundary violations. In addition, Dr. Hobday evaluates and testifies in criminal cases.

Dr. Hobday has co-authored Professionalism in Psychiatry with Dr. Glen Gabbard, and has published many papers. These include papers on self-deception and corruption in physicians in the British Journal of Psychotherapy and the management of sexualized transferences in the American Journal of Psychiatry. She has taught in international settings, including Poland, Italy, and Canada. She also conducts workshops for physicians on professionalism and boundaries in the doctor-patient relationship.

Dr. Hobday received her medical education at University of North Carolina, where she graduated AOA. Her psychiatry residency was completed at Baylor College of Medicine in Houston, and her forensic psychiatry fellowship was completed at Emory University Medical School in Atlanta Georgia.

Hon. Jeffrey J. Jahns, JD

Judge, Kitsap County District Court



Jeffrey J. Jahns was appointed to the Kitsap County District Court in 2009, and elected in 2010. He was raised in Tacoma, Washington. Judge Jahns graduated from the University of Puget Sound in 1978, and from the University of Puget Sound School of Law in 1981. Judge Jahns was a criminal defense attorney in private practice from 1981 to 1994. He joined the Kitsap County Prosecutor's Office in 1995 as a chief deputy prosecutor where he served until his appointment to the bench.

Judge Jahns received the 1995 Kitsap County Bar Association Professionalism Award for his work as a criminal defense attorney. In 2004, he received the Washington State Bar Association Professionalism Award for his work as a prosecutor. Judge Jahns was named a "Super Lawyer" several times by *Washington Law & Politics*.

Judge Jahns has authored many professional articles and publications. His most recent publication, TRAFFIC STOPS IN WASHINGTON STATE BENCH BOOK (Administrative Office of the Courts May 2013), is a comprehensive textbook on Washington search and seizure law from a traffic stop perspective.

Judge Jahns served on the editorial board for the DUI BENCH BOOK (Administrative Office of the Courts October 2013), authoring three chapters for the treatise. Additionally, his 2008 prosecutorial ethics and professionalism training manual, THE QUEST FOR JUSTICE (3rd ed.), continues to be a resource for criminal law practitioners and judges.

Judge Jahns is a Dean for the 2014 Washington Judicial College, a mandatory one week conference all new Washington judges are required to attend. He is also a member of the District and Municipal Court Judges Association's Board of Governors and is his court's Assistant Presiding Judge.

Judge Jahns has been married to his wife Therese since 1981, and has two adult daughters.

Jason T. McGill, JD

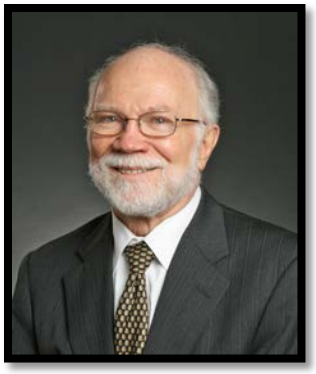
Health Care Policy Advisor to the Governor

Jason McGill has served in both the Gregoire and Inslee administrations as Health Care Policy Advisor. Jason attended Seattle University Albers School of Business and Economics where he earned his BA in Business, Management, and Marketing. He went on to earn his Juris Doctor in law and healthcare from Seattle University School of Law and a leadership certificate from the University of Washington Evans School. Jason served on the Seattle University Alumni Board of Governors for 2012.

Prior to serving in the Office of the Governor, Jason served as an Assistant Attorney General with the Office of the Attorney General before serving as a Medical Administrator with the Department of Labor and Industries.

Hon. Thomas McPhee, JD

Judge (ret.), Thurston County Superior Court



Judge Thomas McPhee served as a superior court judge in Thurston County for more than 22 years until his retirement at the end of 2012. Because the state capitol and most state agencies are located in Thurston County, Judge McPhee's court decides far more appeals from decisions by state administrative agencies than do other courts. He is uniquely qualified to offer to the Commission insights regarding administrative decision making and the appeal process.

After graduating from law school in 1969, Judge McPhee practiced as a trial lawyer, first as an assistant attorney general and then in private practice, until 1990, when he was appointed to superior court by Governor Gardner.

During his 22 years on the bench, Judge McPhee heard and decided numerous administrative law cases of state-wide significance ranging from discharge of dioxins into state waters, the state spotted owl recovery plan, Medicaid reimbursement rules, the constitutionality of funding for special education, and the taxing scheme for construction of Safeco Field. He has heard licensing appeals from all fields of state licensing, including appeals from Commission decisions.

Upon his retirement from the bench, Judge McPhee joined JAMS, the Judicial Arbitration and Mediation Service, where he serves as a mediator of civil disputes, an arbitrator, and as a special master regulating discovery of electronic information is court cases state wide.

This past spring, Judge McPhee was selected as judge of the year by the Washington State Association for Justice, the organization of state trial attorneys.

Charles Meredith, MD

Medical Director, Washington Physicians Health Program

A native of Seattle, Dr. Meredith graduated from medical school in at the University of Wisconsin and completed his general psychiatry residency and addiction psychiatry fellowship at the University of Washington. He subsequently joined the academic faculty at the University of Washington School of Medicine and was on the clinical staff at the Seattle Division of VA Puget Sound. In those capacities he was active in medical student and resident physician education and participated in a number of clinical medication trials for the treatment of stimulant dependence, opioid dependence, and alcohol dependence. In April 2010, Dr. Meredith joined the Washington Physicians Health Program as Associate Medical Director and assumed the role of Medical Director on July 1st, 2012. He provides direct supervision of all WPHP clinical activities, active research projects, and WPHP's educational outreach program in the local medical community.

Originally founded in 1986 by the WSMA, the Washington Physicians Health Program offers confidential intervention and support services for physicians and physician assistants who are temporarily impaired by addictive illness, common psychiatric illnesses, or other conditions leading to recurrent unprofessional behavior. Since the program's inception, WPHP has assisted with the recovery and return to work of thousands of healthcare providers. WPHP is available for physicians and physician assistants and their families, employers, and colleagues who have concerns that a provider may be in need of help.

Jon V. Thomas, MD, MBA

Chair, Federation of State Medical Boards

Past President, Minnesota Board of Medical Practice

After completing residency at Mayo Graduate School of Medicine in Otolaryngology-Head and Neck Surgery in 1993, Dr. Thomas joined a group of three Otolaryngologists in St. Paul, MN. Over the ensuing decade, the group of three has grown to a group of 21 through acquisition and merger. Since 2006, Dr. Thomas has served as President and CEO of the combined entity, Ear, Nose & Throat SpecialtyCare of Minnesota. In 2001 Dr. Thomas earned an MBA in Medical Group Management from the University of St. Thomas in St. Paul, MN.

Shortly after completing the MBA program Dr. Thomas was appointed to the Minnesota Board of Medical Practice by Governor Jesse Ventura in 2001. In 2005, he was reappointed by Governor Tim Pawlenty. After a one year hiatus he was reappointed by Governor Pawlenty for a 3rd term in 2010. Dr. Thomas chaired the Complaint Review Committee from 2003 - 2006. He was elected Secretary of the Board in 2005, Vice President in 2006 and President in 2007 and 2012. As President he also served on a Work Study Group on Controlled Substances. In 2008, he chaired the Policy and Planning Committee. One of his most enlightening experiences was serving on and chairing the Continuing Competency and Maintenance of Licensure Task Force. In an effort to understand the impact of the movement to Maintenance of Licensure, the Minnesota Board set out to examine the potential impact on its physicians and public.

In addition to his service with the Minnesota Board of Medical Practice, he has also been active nationally with the Federation of State Medical Boards. From 2002 - 2004 he served on the Finance Committee. From 2006 - 2007 he served on the Nominating Committee. In May of 2007, he was a lecturer and panelist at the FSMB annual meeting. The title of the presentation was "Ensuring Public Protection in a Dynamic Health Care Delivery Environment." In 2009, he was elected to the Board of Directors. He served as Chair of the Governance of Committee and member of the Executive Committee of the Board of Directors in 2011 - 2012.

Other activities include service on the board of PreferredOne Physician Associates, a large PPO in Minnesota. He continues to serve on its Medical/Surgical Quality Management Subcommittee. In 2006, he was elected to the Senior Management Team of United Hospital, St. Paul's largest hospital. He served in that capacity until 2009. He then went on to serve as Secretary/Treasurer, Vice-Chief and is currently serving as Chief of Staff. He continues to practice full time.

Heather S. Tick, MD, MA

Clinical Associate Professor, UW School of Medicine
Department of Family Medicine, Anesthesia and Pain Medicine

For two decades, Dr. Heather Tick has been a practitioner of integrative medicine, as well as a leading physician, author, lecturer and researcher specializing in Repetitive Strain Injuries (RSI), such as carpal tunnel syndrome, and Musculoskeletal Disorders. Dr. Tick is a currently Clinical Associate Professor at the University of Washington, Department of Family Medicine, Anesthesia & Pain Medicine. She is working at the Center for Pain Relief, at the University of Washington clinic. In the past Dr. Tick has worked as the Director of Integrative Pain clinics in Toronto and Tucson.

Dr. Tick received her Medical Degree from the University of Toronto. She completed her internship at Scarborough General Hospital and her residency at the University of Toronto, Wellesley Hospital. Additionally, she received her Masters of English Literature from the University of California, Irvine.

Dr. Tick takes a unique, holistic approach to the practice of medicine, skillfully integrating traditional methods with alternative treatments, such as Intramuscular Stimulation (Deep Acupuncture), Laser Therapy, Nutraceuticals, Detoxification Therapy, and Bio-identical Hormones. She is considered an authority on the topic of RSI and Workplace Safety, Myofascial Pain Disorders, and Healthy Aging Medicine. An experienced researcher and practicing medical doctor, Dr. Tick is involved in ongoing research projects with several universities.

Michael Tronolone, MD, MMM

Medical Director, the Polyclinic

Dr. Michael Tronolone joined The Polyclinic in 2003 as the clinic's first full-time medic director. Since his arrival, The Polyclinic has grown from 92 to more than 125 physicians, added a hospitalist service, experienced increased patient and physician satisfaction, devised a new quality improvement program to increase colon cancer screening, and improved quality scores for the care of diabetes and heart disease. Dr. Tronolone sits on the Puget Sound Health Alliance Quality Committee as well as the medical advisor committees of several local health plans.

Prior to joining The Polyclinic, Dr. Tronolone worked for Buffalo Medical Group for 14 years. While there he maintained an active clinical practice in Allergy & Immunology and also served on the group's governing board for nine years – three years as chairman. Dr. Tronolone also served as president of IPA of Western New York, representing over 2,000 physicians that contracted to care for over 300,000 member lives. Following his tenure as president of IPA of Western New York, he was appointed to the Board of Directors Independent Health, a not-for-profit HMO that has repeatedly ranked among the best HMO's in national surveys.

Dr. Tronolone received his MD from Georgetown University School of Medicine. He completed a residency in Internal Medicine and a fellowship in Allergy & Immunology at the State University of New York School of Medicine Affiliated Hospitals and is board certified in both Internal Medicine and Allergy & Immunology. In 2001, Dr. Tronolone received his Master in Medical Management (MMM) from Carnegie Mellon University, H. John Heinz I School of Public Policy and Management.