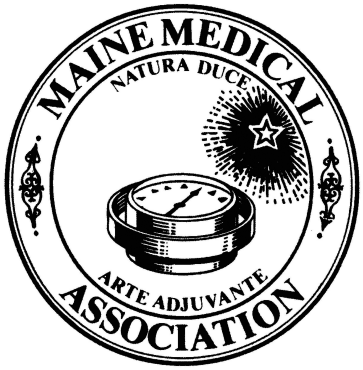
MAINE MEDICAL ASSOCIATION

PAYMENT REFORM READINESS:
A LEGAL TOOLKIT FOR PHYSICIANS

This publication has been prepared by the Maine Medical Association and the law firm of Kozak & Gayer, P.A., solely as an educational resource for physicians seeking an overview of legal considerations related to current health care payment reform initiatives. It is not intended to provide specific legal advice. Physicians seeking specific legal advice relating to the matters discussed in this publication should consult with legal counsel. A directory of Maine attorneys who are knowledgeable in this area and willing to advise physicians can be obtained from MMA. This legal toolkit and the attorney directory were made possible through funding by the "Advancing Payment Reform Strategies in Maine" grant initiative of the Maine Health Access Foundation.



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INTRODUCTION

The U.S. health care payment system is currently undergoing a period of rapid change. Due in part to federal reform initiatives, it appears increasingly likely that the fee-for-service ("FFS") reimbursement model that has prevailed for many years will be replaced, at least in part, by other arrangements that attempt to contain costs and reward higher quality care. These new payment models may pose previously unexplored legal issues. The purposes of this Legal Toolkit include:

- To provide an overview of currently proposed payment reform initiatives;
- To help physicians assess their readiness for payment reform and address gaps;
- To provide an overview of various strategies in response to payment reform initiatives;
- To help physicians recognize some of the legal issues that various payment reform initiatives may raise;
- To help physicians recognize and address some of the legal issues related to various strategy alternatives; and
- To help physicians in discussing these matters with their legal counsel.

EXECUTIVE SUMMARY

Key points discussed in this publication:

- Physicians and practices need to adopt more sophisticated business and clinical management practices to succeed under new payment initiatives – for example, cost accounting, data analytics, and clinical protocols.

- Due to the diversity of current payment reform initiatives, each different model must be considered carefully and judged on its own specifics.

- Many payment reform models involve comparing the physician's costs and outcomes to external benchmarks, and the sources of those external benchmarks are critical.

- Many physicians are changing their practice settings in response to payment reform, but new considerations and challenges will accompany any new practice setting.

- Physician responses to payment reform may implicate legal issues that are unfamiliar to physicians used to the fee-for-service setting.

- Physicians can educate themselves about payment reform through easily available resources.

- Physicians considering their response to payment reform should consult with knowledgeable legal and/or business advisors.

READINESS ISSUES

Although current payment reform initiatives differ, they tend to share some common elements. In particular, they try to make health care providers financially responsible, to some degree, for the cost and quality of care. Accordingly, physicians considering participation in these initiatives should carefully review the business and clinical management tools already in place in their practices, to make sure that they are adequate to support these new responsibilities.

MMA has other educational resources for physicians about business and clinical management tools, which are available on the MMA website (http://www.mainemed.com/cme-education-info/payment-reform). Accordingly, this Legal Toolkit does not attempt to address those issues. Nevertheless, physicians should consider at least the following:

- Does your practice have Electronic Health Record ("EHR") systems in place that can support detailed care management activities?
    - Can your EHR accept and process data furnished by your patients' third-party payors?
    - Does your EHR support data analytics?

- Do you know your practice's actual cost of furnishing each service that you provide?
    - Is cost accounting done on an accrual basis, to deal with costs that will need to be paid at some future date?
    - Is your cost accounting specific to each provider in your practice?

- Do you know the actual FFS reimbursement that your practice receives for each service that you provide?
    - Is the information specific to each payor?
    - Does the information take into account not only the payor's formal fee schedule, but also the net reimbursement after claim edits, payment rules, and other routine adjustments?

- How well do you know the population that your practice serves?
    - What is the size of your patient panel?
    - Is your patient panel representative of the general population in your area?
    - Do you have an actuarially valid projection of your patient panel's likely health needs?

- Will your malpractice insurance cover any new responsibilities that you may assume under payment reform initiatives?

- Do you have established relationships with other providers to whom you refer patients?
    - Do you have information about the cost of the services they provide?
    - Do you have information about their performance on quality measures?

CURRENT PAYMENT REFORM INITIATIVES

Pay for Performance

Basic model

Pay-for-performance ("PFP") reimbursement models are designed to reward providers for achieving certain measures of quality or cost-effectiveness across the relevant patient panel. PFP initiatives tend to be added onto existing FFS reimbursement, and usually represent a fairly small fraction of the total reimbursement for the services provided. The practice's performance on the selected measures is compared to a benchmark, and the practice can earn additional incentive payments if its performance meets or exceeds the benchmark.

Key issues

- What is the benchmark for comparison?
  - Is it appropriate to the patients served by the practice?
  - Is it based on sound data?
  - Are the measures properly risk-adjusted to account for the characteristics of the practice's patient panel?

- What patient panel is subject to the PFP measures?
  - How are patients attributed to the PFP program?
  - Does the practice know in advance which patients are attributed?
  - Will the practice try to achieve the measures for all patients, regardless whether those patients are attributed to the PFP program?

- What quality measures apply?
  - Are the measures "inputs" performed by the practice?
  - Are the measures based on outcomes? If so, how are the outcomes measured?

- What cost containment measures apply?
  - What is the basis for comparison? If it is an "episode of care," how is it defined?
  - How are the costs determined for each episode of care?

- How is the PFP program funded?
  - Are the payments "new money" to the practice, or are they funded from a withhold from the practice's FFS reimbursement?

Bundled Payments

Basic model

In a bundled payment model, the practice receives a single payment for an entire "episode of care." The basic concept is familiar to most physicians, as a bundled payment for physician services is comparable to the single Diagnosis Related Group ("DRG") payment that hospitals receive from Medicare for each inpatient admission.

Key issues

- How is the "episode of care" defined?
    - A time frame?
    - Clinical events?

- Are all of the services within the episode of care under the practice's control?
    - Are the services provided directly by the practice?
    - Does the practice have contractual relationships with other providers of services within the episode of care?
    - How can the practice influence the cost of services performed by other providers within the episode of care?
    - Can the practice exclude another provider from performing services within the episode of care, if the other provider does not appear sufficiently cost-conscious?

- Are bundled payments subject to any adjustments?
    - Are the patient's prior condition and/or clinical risk taken into account?
    - Will any quality measures result in adjustments?

- Will the practice have sufficient access to data?
    - Who is responsible for obtaining and furnishing the data?
    - Will the data be timely enough to allow the practice to manage particular episodes of care?

Capitation

Basic models

Under capitation, a third-party payor makes a regular, prepaid Per Member Per Month ("PMPM") payment for a defined set of services for each patient. Several different capitation models exist:

- Under the Patient Centered Medical Home ("PCMH") model, a primary care practice receives a small PMPM payment, in exchange for which the practice agrees to provide care management services for the patient.

- Under "partial" or "services only" capitation, the practice receives a single PMPM payment for all services performed by that practice for the patient.

- Under "partial global" capitation, the practice's PMPM payment covers not only all services performed by that practice for the patient, but also all services provided by others for which the practice has referred the patient.

- Under "full" or "global" capitation, the PMPM payment is intended to cover all needed health care services for the patient. The provider network is collectively responsible for providing, or paying for, all needed health care services for that patient.

Key issues

- Does the practice, or the provider network, have appropriate insurance licensure?
    - Depending on the level of capitation, the provider may be assuming sufficient "downstream risk" from an insurance entity to require licensure.
    - The practice may be subject to licensure as a Utilization Review entity, if it manages care provided by other providers (for example, "partial global" capitation).
    - If a practice or provider network accepts full capitation, it may be assuming insurance risk, and therefore may be subject to insurance licensure.

- Does the practice have a sufficiently large patient panel to allow for actuarially sound projections of risk?

- Is the practice's financial responsibility for the patient subject to any carve-outs?
    - Can patients receive services for which the practice may be at financial risk due to capitation, but where the practice will not have clinical control?
    - Is the practice's financial responsibility subject to any "stop-loss" provisions?

Shared Savings

Basic model

The "shared savings" concept was introduced under the Medicare Shared Savings Program provisions of the Affordable Care Act, but similar models are also being introduced by other payors. Reimbursement for services to patients is still on a FFS basis. However, for the population of patients "attributed" to a participating provider or provider network (usually, those patients who receive at least half of their care, measured by cost, from that provider or provider network), the actual total annual cost of care for that patient population is compared to a benchmark cost. In this model, the participating provider or provider network is usually referred to as an Accountable Care Organization ("ACO"). If the actual cost is below the benchmark, the ACO receives a share of the amount by which the actual cost is below the "budgeted" amount; if the actual cost is higher than the benchmark, however, the ACO may be obligated to pay for a part of the amount by which the actual cost exceeds the "budgeted" amount.

Key Issues

- What is the patient attribution methodology?
  - Will the practice know in advance which patients are included in its attributed panel?
  - Will there be any exceptions to attribution for patients with specified conditions or risk factors, or who receive a high proportion of their care elsewhere?
  - Will there be any carve-out or stop-loss mechanisms for patients with catastrophic health conditions?

- How are the benchmark costs established?
  - Are benchmark costs based on national, regional, or local comparability data?
  - Is the "budgeted" amount risk-adjusted to reflect the practice's actual attributed panel?

- What quality standards will apply?
  - Will quality measures be within the practice's control, such as routine screenings or other preventive measures?

- What input or control will the practice have over the cost or quality of services provided to its attributed patients by other providers?
  - Will the practice have any ability to give or withhold prior authorization?
  - What incentives to patients will be permitted?
  - Who will determine medical necessity?
  - Will the practice be subject to licensure as a Utilization Review entity?

- For what period of time will the practice participate in the shared savings arrangement?
  - Will the benchmark measures be adjusted during that time?
  - At what point will the practice experience diminishing returns on its participation?

Risk Withholds

Basic model

In a risk withhold, the payor withholds a significant percentage of the reimbursements payable to its participating providers, and deposits the withheld amounts in an escrow account. Risk withholds could be used in connection with any payment mechanism, but they are most commonly associated with FFS reimbursement. If the participating provider network, *as a whole*, achieves certain quality or cost-effectiveness targets, then the withheld amounts are distributed among the providers; if not, then they are forfeited. The purpose is to create a financial incentive for all participating providers in the network to collaborate on meeting the shared goals. If all the participating providers in the network are sharing sufficient financial risk, the network will be regarded as "financially integrated" for antitrust purposes.

Key issues

- How will amounts be withheld?
  - What percentage of FFS reimbursement will be withheld?
  - Can the practice function on the decreased FFS cash flow?
  - Are the withheld amounts held in an escrow account? If so, who controls the escrow account?

- How are the quality and/or cost-effectiveness targets set?
  - Are the measures realistically achievable?
  - Are the targets sufficiently aggressive to create realistic incentives?
  - Are the targets based on comparable benchmark data?

- How is performance measured?
  - Are the performance metrics readily available to all participating providers?
  - Who makes final decisions about whether targets are met?

- What is the distribution mechanism?
  - How long will distribution take?
  - If targets are met, how are distributions allocated among participating network providers?
  - If targets are not met, to whom will the withheld funds be distributed?

Gainsharing

Basic model

"Gainsharing" refers to a model in which a hospital contracts with a practice to manage the cost and quality of a particular department or service; such arrangements may also be termed "service line management" or "clinical co-management." The practice's compensation is based on a portion of the hospital's cost savings, measured against a cost benchmark, as long as quality targets are met. Because the U.S. Department of Health and Human Services, Office of the Inspector General ("OIG") has interpreted the Civil Money Penalties statute to prohibit the payment of any financial incentive by a hospital to a physician to limit the goods or services furnished to a Medicare beneficiary (regardless of medical necessity), gainsharing models tend to focus on standardizing supplies, devices, and drugs, and on reviewing processes so that, for example, packaged items are only opened as needed, rather than routinely.

Key issues

- What quality targets must be met?
  - Will achievement of these targets be within the practice's control?

- How will the benchmark costs be determined?
  - Will the practice have access to the benchmark data?
  - Will the practice have sufficient data to track current costs?

- What tools will the practice have to manage costs?
    - How will the practice standardize the hospital's supplies?
    - Will the practice have sufficient authority to manage the delivery of services by hospital support staff?
    - If other physicians who are not a part of the practice will be practicing in the service or department, will they cooperate with the management initiatives?

- Will the arrangement be reviewed for legal compliance with the Civil Money Penalties statute?
    - Will the parties seek an OIG Advisory Opinion?
    - If not, is the arrangement sufficiently similar to a previously approved gainsharing arrangement?

STRATEGIES FOR RESPONDING TO PAYMENT REFORM

In response to the anticipated challenges of new payment reform initiatives, which appear likely to include substantial needs for business management and for access to capital, physicians are exploring a number of different strategies. Each of these strategies involves both legal and business issues, not to mention the physician's own preferences and practice style.

Cash/"Concierge" Practice

A few physicians have opted out of payment reform initiatives, essentially by opting out of the payment system entirely. Some physicians use a cash-only practice model, in which they do not participate with any third-party payors; others participate in a prepaid "concierge" arrangement whereby they provide an enhanced array of services to a limited panel of patients. Both of these strategies tend to work better for primary care physicians than for specialists (with the possible exception of psychiatrists using a cash-only model).

Both these strategies remain controversial, due to the perception that they may exclude patients who are unable to afford out-of-pocket payment. Advocates of the cash-only practice model suggest that eliminating the overhead associated with third-party payor participation may allow physicians to charge more affordable fees, but little evidence is available to suggest whether cash-only practices can successfully serve patients across the economic spectrum. Advocates for the concierge model generally concede that it is a niche market for more affluent patients (sometimes in the form of an additional benefit for highly-compensated executives); if broadly adopted, therefore, it could adversely affect availability of care.

<u>Cash Practice</u>

- Physicians (and mid-level providers) do not participate with any third-party payors
- Practice develops own fee schedule
- If patients have third-party payors, some practices will assist patients in submitting claims for reimbursement – but patients pay practice directly, without awaiting reimbursement
- Payment may be required at time of service
- Feasibility depends on patient demographics
- Possible difficulties in collection

<u>Concierge Practice</u>

- Many different models; need to review specifics carefully

- Basic feature is prepaid monthly or annual fee for all included services
- Typically offer higher level of primary care service
- Service models may be offered by national companies
- May or may not involve participation with third-party payors
- Prevention and wellness services often featured

"Augmented" Small Practice

For physicians who wish to remain in a solo or small group practice, and are willing to take on the added responsibilities of operating under payment reform initiatives, upgrading the infrastructure of a small practice can be a viable strategy. The key focus must be on retaining control of as much of the health care expenditures as possible for each patient, so as to maximize cost-effectiveness. (An oft-repeated maxim about payment reform is that in order to remain viable, providers will need to "function at the top of their license.") Necessary elements of such a strategy are likely to include:

- A relatively sophisticated EHR system
- Maintaining a patient registry that tracks all chronic health conditions and related care and treatment
- Use of clinical protocols and guidelines, often via "expert assistance" functions embedded in the EHR or patient registry
- Minimizing specialty referrals, and maximizing in-house procedures and interventions
- Leveraging non-physician personnel to add value:
    - Physician Assistants and Nurse Practitioners practicing as autonomously as possible consistent with applicable supervision requirements
    - Care managers to improve patient compliance with care coordination, wellness and prevention measures, and chronic disease protocols
    - Behavioral health providers to coordinate primary care with mental health and/or substance abuse treatment needs
- Benefits: readiness to participate in risk-sharing models
- Risks: additional costs may not be covered by revenues

Larger Group Practice

By forming larger group practices, physicians hope to achieve economies of scale, including sufficient capital to support EHR investment, more efficient facilities, professional management

staff, purchasing power, and other similar infrastructure. Larger group practices typically maximize their physician's in-house referrals for ancillary services (lab, imaging, etc.). All of the above strategic considerations for a small practice still apply to larger groups, as well as the following:

- Will the group be sufficiently large that it may raise antitrust concerns about the use of its market power?

- Will the group have long-term contractual commitments to a practice management company or management services organization?

- Is the group's governance sufficiently accountable to the group's physicians? Is it capable of making timely, appropriate strategic decisions?

- Is the group's management cost-effective? Can it staff its own HR, finance and accounting, compliance, IT, and similar functions?

- Will the practice have a sufficiently large patient panel to permit actuarially sound participation in risk-sharing payment models?

Independent Practice Association

An independent practice association ("IPA"), sometimes referred to as a "group practice without walls," is a network of otherwise independent physicians or group practices that affiliates for specific purposes – most often, as a vehicle for negotiating payor contracts. Through joining together in an IPA, the physicians hope to maximize their bargaining leverage. Unfortunately, many IPAs have run afoul of the antitrust laws, because it is *per se* unlawful for competing physicians to engage in joint contract negotiations unless they share sufficient risk to be regarded as financially integrated, or implement sufficient common practice management to be regarded as clinically integrated. As an alternative, some IPAs used a "messenger model," whereby the physicians are technically not negotiating jointly, but instead the IPA is merely acting as a "messenger" on behalf of individual physicians; however, in a number of instances, the antitrust authorities have determined that the "messenger model" was actually a covert form of joint negotiation. Key points for physicians considering an IPA include:

- Are there strong business reasons for forming an IPA, other than to negotiate payor contracts?

- What level of capital investment will participating physicians need to make?

- Are the physicians in the IPA prepared to share financial risk through:
    - Substantial risk withholds, to be distributed based on the performance of the IPA as a whole?
    - Capitation – PCMH, limited, partial global, or global?
    - Shared savings, with risks and rewards based on the performance of the IPA as a whole?

- Are payors in the relevant market prepared for risk contracting with an IPA?

- Is the IPA prepared to engage in clinical integration through:
  - A common EHR;
  - A full-time Medical Director;
  - Clinical guidelines and protocols;
  - Disease registries;
  - Regular reports to participating physicians on quality and outcomes; and
  - Care coordination and management?

Physician-Hospital Organization

A physician-hospital organization ("PHO") is a provider network consisting of one or more hospitals, the physicians employed by the hospitals or their affiliates, and independent physicians or practices (with membership typically being restricted to physicians on the hospitals' Medical Staffs). Because hospitals usually already have sophisticated finance, accounting, and EHR infrastructure in place, a PHO may allow participating physicians a relatively quick path to financial and/or clinical integration. With respect to independent physicians and practices, however, a PHO faces the same antitrust issues as an IPA. Additionally, key points for physicians considering participation in a PHO include the following:

- What level of capital investment will physicians be required to make in the PHO?

- If the hospital is tax-exempt, has the PHO structure been reviewed to assure that participating physicians will not be considered to be receiving an excess private benefit?

- What is the PHO's governance structure? Will participating independent physicians and practices be adequately represented in strategic decision-making?

- Have the structure and operations of the PHO been reviewed to assure that its activities will not be deemed to violate laws governing referrals between physicians and hospitals?

- Will PHO physicians have access to the hospital's EHR? Will all PHO physicians be on the same EHR platform?

Hospital System Affiliation

Hospitals have recently been employing an increasing number of the physicians on their Medical Staffs, either directly or through an affiliate corporation. This alternative can be attractive to independent physicians who are seeking increased financial security, as well as the ability to focus on the clinical aspects rather than the business aspects of their practice. However, hospitals, being larger organizations, typically have a more formal management structure than most independent physicians may be used to, and not every physician fits comfortably into a hospital's corporate culture. Apart from matters of personal style and preference, however,

physicians considering affiliation with a hospital system through employment should consider the following points:

- Will the hospital's EHR adequately support the physician's practice needs?

- How are physicians consulted or involved in matters related to the management of their practices?

- How do physicians receive feedback on their clinical performance?
    - Does the hospital have a physician Medical Director for its physician practice?
    - Are non-physician managers involved in decisions that affect clinical practice?
    - Will physicians receive regular feedback about clinical outcomes and other quality measures?
    - Do clinical performance measures affect the physician's compensation?

- Will the physician's practice become "provider-based" for reimbursement purposes, and if so, how will patients respond to receiving new charges for facility fees, in addition to charges for the physician's professional fees?

- Does the hospital or health system have a clear strategy for responding to payment reform initiatives?

- Does the hospital system have a clear strategic vision for addressing anticipated changes due to payment reform?

- Is the hospital system on a financially sound footing? Does it have adequate reserves to support participation in risk-based payment systems?

- How will physician compensation be determined? If compensation is currently productivity-based, is there a plan for transitioning to a compensation system that rewards compliance with the goals of payment reform – that is, better outcomes for lower cost?

KEY LEGAL ISSUES

Physician participation in payment reform initiatives may raise a broad variety of legal issues, including, among many others, identifying and forming a proper business entity to serve as a practice vehicle; compliance with specific licensure requirements; state prohibitions on the corporate practice of medicine; and tax and other financial planning for physicians and practices. The discussion below is intended only as an overview of a few selected topics that are most likely to arise specifically in this context. As noted above, physicians seeking specific legal advice relating to any of these matters should consult with knowledgeable legal counsel. References to some of the key legal authorities are included at the end of this Legal Toolkit under "Additional Resources."

Antitrust

Physicians and practices often feel disadvantaged when negotiating individually with payors. However, if independent practices negotiate jointly with payors, they risk liability as a "contract, combination, or conspiracy in restraint of trade" under federal and state antitrust laws. However, joint negotiation is permissible where it is ancillary to a legitimate joint venture – that is, where the parties have entered into sufficient financial or clinical integration to be viewed as a single, common enterprise.

If a provider network shares financial risk through capitation, shared savings, or risk withholds, then it likely will be viewed as sufficiently financially integrated. Other financial integration models are also possible, but require careful scrutiny.

To achieve sufficient clinical integration to support joint negotiation, a provider network must make a major investment in shared clinical systems – for example, a common EHR, clinical pathways and guidelines for common conditions, a network-wide medical director, quality reporting and feedback, and rigorous peer review.

A practice that negotiates individually with payors is unlikely to face antitrust issues. Before participating in any provider network that engages in joint negotiation with payors on behalf of its members, however, the practice should assure itself that the network is sufficiently integrated.

The U.S. Department of Justice and Federal Trade Commission ("FTC"), which are the leading antitrust enforcement agencies, have issued a great deal of helpful guidance related to antitrust issues in health care. The FTC's 2005 decision in *North Texas Specialty Physicians* provides some particularly helpful background about issues facing IPAs and similar provider networks. Because *North Texas Specialty Physicians* was the first fully-litigated case involving an IPA in over twenty years, the FTC took the opportunity to provide the following guidance:

- Rather than condemning physician network activities as price fixing and therefore *per se* illegal, the FTC will use a more flexible "quick look" analysis to see whether the network can advance any plausible argument that its activities enhanced efficiency (*i.e.*, increasing output, or improving quality, service, or innovation).

- The FTC condemned the following:
  - Polling participating providers to determine minimum acceptable reimbursement rates, and then reporting the poll results back to the participating providers;
  - A participating provider agreement that granted the network the exclusive right to negotiate with payors on the provider's behalf, and committed the provider to refrain from considering any offers from payors other than through the network;
  - Powers of attorney granted by participating providers to the network, appointing the network as their sole bargaining agent;
  - Termination of participating providers' participation in certain payor contracts, in order to exert bargaining leverage on payors; and
  - Purported use of a "messenger model" that in reality allowed the network to negotiate (and exert collective bargaining power) on behalf of its members.

- The FTC found that the network provided no proof that its activities promoted improvements in cost and quality:
  - The network did not apply any of the quality or utilization measures used in its one risk contract to its non-risk contracts; and
  - The network did not engage in any significant elements of clinical integration: *i.e.*, exchange of clinical information, coordination of treatment, development of protocols, or monitoring of compliance.

- The FTC listed a number of elements that it would consider procompetitive justifications for network activities:
  - Disease management programs or patient registers to improve health care quality for patients with specific, long-term conditions;
  - Maintaining and disseminating patient treatment and outcome data;
  - Utilization management programs; and
  - Enforcing adherence to clinical guidelines and protocols.

- The FTC provided further guidance for implementing the "messenger model" in ways that would be unlikely to violate the antitrust laws.

- The FTC cited certain activities that could support a claim of clinical integration, including analyses of, among other things, utilization practices, physician care across practice areas, coding patterns, referral patterns, patterns of under-serving patients, trends in ancillary costs, comparisons of care for different patient populations, and report cards comparing physician performance against benchmarks, guidelines, and protocols.

In summary, the FTC used its decision in *North Texas Specialty Physicians* as an opportunity not only to address the specific unlawful conduct at issue in that case, but also to give reassurance to provider networks that many network activities would be viewed in a positive light.

Insurance Licensure and "Downstream Risk"

Certain activities associated with payment reform initiatives may require insurance licensure. Assuming financial risk for the cost of services that a practice itself provides is generally viewed as "business risk" rather than "insurance risk," and should not require licensure. Assuming financial risk for the cost of services provided by others, however, could be deemed to be the business of insurance.

The Maine Insurance Code governs the assumption of "downstream risk" by physicians and other providers. While the details are complicated, the basic concept is simple: if an entity that is "downstream" of a licensed insurance carrier assumes substantial financial risk for the cost of services that the entity does not itself provide, then the arrangement is subject to review and approval by the Superintendent of Insurance.

In some cases, the provider (or more likely, a provider network) will not merely be assuming a "downstream" risk from a licensed insurance carrier, but will itself be assuming full insurance risk. If so, then the provider network will effectively have become an insurance entity itself, and will be subject to insurance licensure – most likely as a Health Maintenance Organization ("HMO"). Insurance licensure requires compliance with a number of regulatory requirements, but the major concern of the Bureau of Insurance is likely to be the entity's financial soundness, as it could have exposure to significant financial demands in the event of high-cost patients or treatments.

Medicare Compliance

The Medicare statute contains numerous provisions regulating payment arrangements. Many of these provisions were originally aimed at preventing inappropriate over-utilization of health care goods and services in a FFS environment – for example, excessive referrals for diagnostic services in which the referring physician has an investment interest. The breadth and complexity of these provisions can lead to legal difficulties for new payment models. While it may be arguable that these provisions will not be as necessary in a risk-based payment environment, nevertheless physicians will still need to comply with them.

Moreover, as these provisions affect any services for which the Medicare or Medicaid programs may make payment either in whole or in part, their reach can be unexpectedly broad, especially as more Medicare-eligible individuals remain in the workforce and have Medicare as a potential secondary payor in addition to their primary health insurance coverage.

<u>Stark</u>

The Stark law prohibits physician referrals for certain "designated health services" if the entity that provides those services has a financial relationship with the physician, unless the terms of a specific exception are met. The exception requirements are detailed and specific, and are set forth in rules promulgated by the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"). Accordingly, any payment model needs to be reviewed carefully to determine whether it may create a direct or indirect financial relationship

between physicians and providers of designated health services, and if so, whether a Stark exception applies. The key Stark exceptions applicable to various practice alignment strategies are:

- The employment exception, which requires *bona fide* employment and compensation consistent with fair market value;

- The group practice exception, which requires a single legal entity that has at least two physicians, each of whom provides through the group (i) substantially the full range of patient care services that the physician routinely furnishes, and (ii) substantially all the physician's patient care services, and that acts as a unified business; and

- The personal service arrangements exception, which requires a signed written agreement for specified services, with compensation set in advance that does not exceed fair market value and does not vary with the value or volume of any referrals or other business generated between the parties.

Anti-Kickback

The Medicare Anti-Kickback Statute prohibits knowingly or willfully offering or accepting any remuneration as an inducement to make a referral for goods or services for which the Medicare or Medicaid programs may pay in whole or in part. Because of the breadth of this prohibition, the statute also provides for "safe harbor" treatment of certain arrangements that will not be deemed to create a prohibited remuneration.

The "safe harbor" rules are promulgated by OIG, rather than by CMS. As with the Stark exceptions, the requirements of the anti-kickback safe harbors are detailed and specific; unlike Stark, however, compliance with a safe harbor is not required, and many arrangements that do not fit within a safe harbor are nevertheless lawful. Several of the anti-kickback safe harbors are directly aimed at encouraging alternative payment models. The key anti-kickback safe harbors applicable to various practice alignment strategies are:

- The safe harbor for personal services and management contracts, which has requirements similar to those of the Stark personal service arrangements exception;

- The employment safe harbor, which has requirements similar to those of the Stark employment exception;

- The safe harbor for investments in group practices, which is comparable to (though much less detailed than) the Stark group practice exception;

- The safe harbor for price reductions offered to a health plan, which requires a written agreement between the health plan and the contracted health care provider that meets detailed standards;

- The safe harbor for price reductions offered to eligible managed care organizations, which requires a written agreement between the managed care organization and the contracted health care provider that meets detailed standards; and

- The safe harbor for price reductions offered by contractors with substantial financial risk to eligible managed care organizations, which (like the above safe harbors) requires a written agreement between the managed care organization and the contracted health care provider that meets detailed standards, but which also lists those payment methodologies that constitute "substantial financial risk."

Civil Money Penalties

While the Medicare statute contains numerous items that could be the basis for civil money penalties, the phrase "Civil Money Penalties statute" often refers to a specific aspect of the Medicare statute: the prohibition on "reverse kickbacks" from hospitals to physicians, that is, any financial inducement to reduce the amount of goods or services provided to Medicare beneficiaries, regardless of medical necessity. Any innovative payment model needs to be reviewed carefully for compliance with the Civil Money Penalties statute; in particular, gainsharing arrangements and, to a lesser extent, shared saving programs may implicate this prohibition. If CMS has approved an ACO arrangement under the Medicare Shared Savings Program, that approval protects the arrangement from being deemed to violate the "reverse kickback" provision.

Beneficiary Inducement

The Medicare statute prohibits providers from offering most kinds of inducements to Medicare beneficiaries as an incentive to use the provider's services. In a payment model that is based on network arrangements, this prohibition can make it difficult to encourage patients to use network providers. This limitation can be a particular concern under shared savings models. For that reason, the Medicare Shared Savings Program includes specific requirements for permitted incentives. If CMS has approved an ACO arrangement under the Medicare Shared Savings Program, that approval protects the arrangement from being deemed to violate the beneficiary inducement provision.

Data Ownership and Access

Innovative payment models may generate a great deal of data beyond the traditional medical and billing records. In risk-based payment environments, information about utilization, quality, cost, and other issues may take on significant value. It is important, therefore, to clarify ownership of the various kinds of data that may be generated. Ideally, physicians and practices will be able to negotiate to retain ownership of information that they generate themselves or that they bear the burden of obtaining from third parties; however, participation agreements may well contain provisions that state otherwise.

Confidentiality, Privacy, and Security

As noted above, payment reform initiatives are likely to increase the volume of data exchanged among plans, providers, and others in the health care system, and a significant fraction of the data will likely be protected under HIPAA and Maine law. Both HIPAA and Maine law generally permit the sharing of protected health information between health care providers and payors without an authorization; under new payment models, however, such information may well be shared with other parties, some of which may not fit conveniently into existing categories where disclosure of information is routinely permitted. Physicians and practices will need to assure that all needed authorizations for disclosure are in place, and that any use or disclosure of information without an authorization is covered by an applicable exception. Among other things, physicians and practices will need to review and update their HIPAA business associate agreements, and should also determine whether any provider networks in which they participate are in compliance with HIPAA requirements for an "organized health care arrangement."

Data security is an increasing concern. Most new payment models are likely to involve substantial exchanges of data in electronic form. Physicians and practices should consider at least the following issues:

- Is there a robust encryption system in place for electronic data?
- Does the physician's or practice's insurance coverage include data breach liability?
- Who administers data security matters, and will the physician or practice be assuming new responsibilities in this area?

Patient Attribution

Where financial performance under a payment model will depend on what patients are attributed to the physician or practice, it is critical to understand the attribution methodology. Otherwise, the physician or practice cannot obtain any actuarial estimate of the financial risk being assumed. Under capitation, the physician or practice should be receiving regular reports explaining the capitated population for which PMPM payments are being made. In a shared savings model, however, the determination of which patients will be attributed to the physician or practice may be made well after the fact. (This feature has been a major source of criticism of the Medicare Shared Savings Plan model.)

If patient attributions are known in advance, the physician or practice can apply specific management guidelines to those patients who are on the attributed patient panel, without needing to extend the same measures to all other patients in the practice. If not, however, then all patients in the practice (or, at the very least, all patients having that payor, such as all Medicare FFS patients) will need to be treated as if they were subject to the same measures that will be applied to the attributed patient population.

Allocation of Responsibilities

Under FFS, the division of responsibilities between the payor and the provider is theoretically clear: the payor is responsible to make payment decisions and to pay claims, and the provider is responsible for furnishing the goods or services. Payors do not practice medicine, and providers do not make coverage decisions. In reality, that seemingly clear-cut distinction has been blurry even under most existing FFS arrangements, but payment reform will likely make it even more so.

Physicians and practices can no longer rely upon traditional assumptions about the scope of their responsibilities; rather, those responsibilities should be expressly allocated in the participation agreement, and each different arrangement will likely carry a different allocation of responsibilities. Key matters that should be addressed by contract include:

- Who makes medical necessity determinations?
    - How will such determinations affect payment?
    - What is the review or appeal process?

- Who must authorize referrals?
    - What items or services are subject to referral authorizations?
    - If a patient receives items or services without a proper referral, who bears the financial risk – the patient, the entity that furnished the item or service, or the physician or practice responsible for coordinating the patient's care?

- Who provides utilization review ("UR")?
    - How do physicians or practices receive feedback on UR findings?
    - Will UR findings affect payment?
    - Will UR findings affect participation?

- Who provides quality oversight, sometimes referred to as quality assurance ("QA") or quality management ("QM")?
    - How do physicians or practices receive feedback on QA/QM findings?
    - Will QA/QM findings affect payment?
    - Will QA/QM findings affect participation?

Eligibility Verification

Even if a patient presents a card identifying him or her as a plan beneficiary, the provider is vulnerable to a subsequent determination by the plan that the patient was not enrolled at the time of the service. The plan is in a far better position than the provider to determine whether the patient is properly enrolled. Therefore, participating providers should insist on a provision in the participation agreement that requires the plan to furnish a binding coverage determination at the time of the service.

In theory at least, the risk of retroactive disqualifications should be lower under payment systems in which the physician or practice assumes care management responsibilities for a panel of

patients. Capitation payments for such patients should generally be made in advance, and the physician or practice should develop more familiarity with patients in the panel. However, demands for repayment of capitation payments remain possible, and physicians and practices should review contract language carefully to make sure that this risk is minimized.

Liability Insurance Coverage

Physicians and practices are accustomed to maintaining professional liability insurance coverage, but as they enter into new payment arrangements that may require them to take a more active role in coordinating care for their patients, they need to be aware that professional liability insurance generally excludes coverage for "managed care" activities. Physicians and practices should:

- Review current insurance policies, coverage limits, and exclusions;
- Identify new responsibilities that the physician or practice will be assuming under new payment arrangements;
- Consult with an experienced insurance consultant or broker; and
- Make sure that appropriate coverage is obtained, whether through a new "errors and omissions" policy or though a "managed care activities" endorsement on an existing liability policy.

Indemnification

Indemnification is a contractually assumed duty to defend another party, or to pay damages on behalf of that party, in the event of a claim by a third party. Because indemnification liability is contractual, it is almost never covered by insurance. Many standard participation agreements will contain indemnification language, but it is rarely in the provider's best interest to accept an indemnification liability. A better approach is for each party to bear its own risks, with appropriate insurance coverage in the case of a provider (the carrier is already a risk-bearing entity).

Negotiating satisfactory indemnification provisions may require legal counsel. The physician or practice should also review liability insurance policies to determine:

- Whether indemnification liability is specifically excluded; and
- Whether assuming an indemnification liability may jeopardize coverage under the policy as a whole.

Fraud

Under FFS, fraud most commonly involves claiming reimbursement for goods or services that were not actually provided, that were not medically necessary, or that were not as claimed.

Innovative payment models tend to reduce the financial incentive for inflation of claims. Misrepresentations for the purpose of obtaining an improper financial gain will continue to be fraud, but the specifics will differ depending on the payment model. Activities that will continue to be scrutinized as fraud under new payment models include:

- Falsifying information to justify higher payments of any kind;

- Paying or receiving inappropriate inducements to reduce the services provided to covered individuals; or

- Providing inappropriate incentives to patients to use the physician's or practice's services rather than going out of network.

Ethics

Innovative payment models may pose ethical issues in new or more challenging ways. Examples include:

- What effect will the physician's decisions have on payment?
    - Could the physician's clinical judgment be affected by incentives to withhold or minimize treatment?
    - Does the payment mechanism appropriately encourage the physician to involve other providers in the patient's care?

- Could a payor's guidelines for medical necessity or utilization review override the physician's clinical judgment?
    - Is the physician subordinating his or her clinical judgment to that of a non-physician?
    - Does a physician have an ethical obligation to advocate with the payor for a particular approach to the patient's care or treatment?
    - If so, at what point has the physician fulfilled that responsibility?

- Are the goals of the "Triple Aim" of payment reform (improving satisfaction and quality of care, improving overall population health, and reducing the per capita cost of health care) consistent with the physician's duties to each individual patient?

- To what extent does a physician assume ethical obligations for patients attributed to the physician's panel?
    - Must the patient actually have contacted the physician, or does the mere fact of attribution create responsibilities?

- Does a physician's change of practice model create a risk of abandonment of existing patients?

ADDITIONAL RESOURCES

General Resources

Because of the sheer volume of published material on health care payment reform, finding clear guidance (especially for those seeking introductory materials) can be challenging. Some of the more accessible and helpful sources available to physicians include the following:

Maine Medical Association
MMA maintains a "Payment Reform" page (under "CME & Education Info"), with links to many useful resources:
http://www.mainemed.com/cme-education-info/payment-reform

American Medical Association
AMA's "Physician Payment Reform" page compiles numerous reports from the AMA's Council on Medical Service, and also provides external links to other resources:
http://www.ama-assn.org//ama/pub/about-ama/our-people/ama-councils/council-medical-service/reports-topic/physician-payment-reform.page

U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services
The Center for Medicare & Medicaid Innovation, within CMS, offers information about payment reform initiatives under the Medicare and Medicaid programs:
http://innovation.cms.gov/

American Health Lawyers Association
AHLA maintains a "Healthcare Reform Legal Essentials" page, focusing on legal developments in connection with the Affordable Care Act:
http://www.healthlawyers.org/HCR/Pages/default.aspx

Internal Revenue Service
Because many provisions of the Affordable Care Act are tax-related, the IRS provides a page on "Affordable Care Act Tax Provisions" with detailed guidance, much of which is fairly technical in nature:
http://www.irs.gov/uac/Affordable-Care-Act-Tax-Provisions-Home

Federal Trade Commission
The FTC maintains a page on "Competition in the Health Care Marketplace," with resources on antitrust guidance and links to all FTC health care antitrust enforcement actions:
http://www.ftc.gov/bc/healthcare/index.htm

Center for Healthcare Quality & Payment Reform
CHQPR, a nonprofit organization that advocates for comprehensive change in the health care payment system, offers a number of helpful publications:
http://www.chqpr.org/

Legal References

The sheer volume of statutes, rules, interpretive statements, and case law affecting the health care system can make it difficult to locate the specific sources of authority on particular topics. The authorities listed below are by no means exhaustive, but should provide a starting point for those seeking authoritative guidance:

Affordable Care Act
The Patient Protection and Affordable Care Act (Public Law 111-148), and its companion legislation, the Health Care and Education Reconciliation Act (Public Law 111-152), were enacted together as 124 Stat. 119 (2010).

Medicare Shared Savings Program
The Medicare Shared Savings Program is authorized under section 3022 of the Affordable Care Act, now codified at 42 U.S.C. § 1395jjj.

Gainsharing
The portion of the Medicare civil money penalties statute that affects gainsharing is "Payments to induce reduction or limitation of services," 42 U.S.C. § 1320a-7a(b).

Antitrust
The key antitrust law affecting physicians is section 1 of the Sherman Act, 15 U.S.C. § 1.

The Department of Justice and Federal Trade Commission *Statements of Antitrust Enforcement Policy in Health Care* (1996) are available at:
www.ftc.gov/bc/healthcare/industryguide/policy/index.htm.

The DOJ/FTC *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (2011) is available at:
http://www.ftc.gov/bc/healthcare/aco/.

The entire FTC docket for the case discussed in the text, *In the Matter of North Texas Specialty Physicians*, is available at: http://www.ftc.gov/os/adjpro/d9312/index.shtm. The FTC's opinion discussing the antitrust issues is dated December 1, 2005.

Insurance and "Downstream Risk"
Maine's Insurance Code is Title 24-A of the Maine Revised Statutes. The "downstream risk" provision is 24-A M.R.S.A. §§ 4331-4343.

Stark
The Stark statute is 42 U.S.C. § 1395nn. The Stark rules are at 42 C.F.R. § 411, Subpart J (§§ 411.350-411.389).

Medicare Anti-Kickback Statute
The Medicare Anti-Kickback Statute is 42 U.S.C. § 1320a-7b(b). The "safe harbor" rules are at 42 C.F.R. § 1001.952.

Beneficiary Inducement

The portion of the Medicare civil money penalties statute that affects inducements to beneficiaries to use a certain provider or supplier is 42 U.S.C. § 1320a-7a(a)(5).

Confidentiality, Security, and Data Breach Notification

The HIPAA Privacy, Security, Enforcement, and Breach Notification Rules are at 45 U.S.C. Parts 160 and 164. The general Maine health care information confidentiality statute is 22 M.R.S.A. § 1711-C.

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Mr. Townsend is a member of the Health Law section of the Maine State Bar Association, the Antitrust and Health Law Sections of the American Bar Association, and the American Health Lawyers Association. He is a frequent presenter at seminars on health law matters, and a former adjunct professor in the graduate program in health policy and management offered through the Edmund S. Muskie School of Public Service at the University of Southern Maine, where he developed and taught a course in health law. Mr. Townsend is a graduate of Harvard College and the University of Maine School of Law, and is admitted to practice in both state and federal courts in Maine, and in the states of New Hampshire, Vermont, and New York.