

**American Hospital Association
Comments
to
the Senate Finance Committee
on
Transforming the Health Care Delivery System:
Proposals to Improve Patient Care
and Reduce Health Care Costs**

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on your April 29 policy options paper on delivery system reforms.

Hospitals support the enactment of comprehensive, meaningful health care reform legislation this year. Over the past several years, the AHA Board of Trustees has worked to develop a framework for health reform. The board spoke with hundreds of hospital leaders, held public listening sessions and convened more than 100 organizations representing consumers, health advocacy groups, business, insurers, providers, unions and others to identify those changes in law and regulation necessary to improve health and health care in America. The result – *Health for Life: Better Health. Better Health Care.* – identifies five essential elements of reform:

- 1) Health coverage for all, paid for by all;
- 2) A focus on wellness;
- 3) The most efficient, affordable care;
- 4) The highest quality care; and
- 5) The best information.

The *Health for Life* framework identified detailed policy options within each of the five elements above, and we are pleased that a number of its ideas are reflected in the Senate Finance Committee's (SFC) options paper. Hospitals are committed to being an active and engaged partner in efforts to achieve health care reform. Ensuring health coverage for all is absolutely critical, and delivery system reforms will be necessary to achieve cost savings to expand coverage and encourage high-quality, efficient and affordable care.



The AHA commends the Senate Finance Committee (SFC) for including a number of important policies in its options paper, including developing a comprehensive strategy to address workforce shortages, redistributing unused graduate medical education slots to increase access to primary care and banning, under certain conditions, physician self-referral to a hospital in which the physician has an ownership interest.

Hospitals support delivery system changes to improve quality and efficiency. We also support the principles of value-based purchasing (VBP), bundling payments and decreasing hospital readmissions, as these provisions have the potential to improve care coordination, provider collaboration and chronic care management. At the same time, some of the specific provisions in the options paper could negatively impact the Nation's hospitals. And, in order for these policies to be successful, the SFC and Congress must make changes to current laws and regulations to allow providers to integrate their clinical activities and work together in the patient's best interest.

Implementation of the VBP, bundling and readmission provisions, as drafted, would result in payment cuts to an already underfunded Medicare payment system. The Medicare Payment Advisory Commission (MedPAC) projects that hospitals will have a *negative* 6.9 percent Medicare margin in 2009 – down from a *positive* 6.2 percent Medicare margin in 1999 – the lowest level in more than a decade. According to AHA annual survey data, 58 percent, or 2,840 hospitals, were not paid their cost for serving Medicare patients in 2007. The federal fiscal year (FY) 2010 inpatient prospective payment system (IPPS) proposed rule would further reduce hospital payment by \$22 billion over the next 10 years. Hospitals cannot withstand additional cuts.

The AHA appreciates the gradual timelines and phase-in policies proposed to implement delivery system reforms, but we are concerned about the interactive and cumulative effect of the proposals. Some hospitals, especially those in integrated delivery systems, will be better able to adopt reforms than others. Time will be needed for other hospitals to change their infrastructure and organize themselves into integrated delivery systems. Most of the reforms start in FYs 2013-2015, while hospitals will be working to implement health information technology (HIT). Safety-net hospitals, which serve large minority and low-income populations, could be disproportionately impacted by the VBP, bundling and readmission provisions as drafted. Small and rural hospitals, which have less volume and larger-than-average shares of Medicare beneficiaries, also could be disproportionately affected by significant payment changes or cuts to the Medicare program.

We look forward to working with the SFC and other policymakers to develop the best policy changes possible to achieve better health and health care in America. Following are our detailed comments on key provisions affecting hospitals. While not specifically addressed in your options paper, we include recommendations related to clinical integration and administrative simplification, as we believe that these two components are critical to successful delivery system reform.

HOSPITAL VALUE-BASED PURCHASING

The SFC proposes to establish a VBP program that would pay all inpatient acute-care PPS hospitals for their actual performance on quality measures, rather than the reporting of those measures, beginning in FY 2013. Certain hospitals would be excluded, including those that do not have a sufficient number of patients within the related conditions.

Measures would be selected from those used in the current Medicare pay-for-reporting program, and could be expanded after the first year. Funding for the program would be generated by reducing all Medicare inpatient PPS Medicare-severity diagnosis-related group (MS-DRG) payments to participating hospitals by 2 percent in FY 2013, 3 percent in FY 2014, 4 percent in FY 2015 and 5 percent in FY 2016 and beyond. A hospital that meets or exceeds a performance standard would be eligible to earn back only the money initially withheld.

A hospital's single, composite performance score would be used to determine whether the hospital meets an overall performance standard. Hospitals would be rewarded for quality improvement or quality attainment, whichever level is higher. A hospital with a score in the bottom 25th percentile would not receive back any of the VBP money withheld. A hospital with a score in the 26th to 75th percentile would receive payment based on a sliding scale, while a hospital with a score above the 75th percentile would receive its withheld amount. Unused incentive funds would be returned to the Medicare Trust Fund.

America's hospitals have long been committed to improving the quality and safety of patient care. We support the concept of aligning payment with high-quality patient care, but given the complexity and magnitude of the program, we encourage the SFC to move forward thoughtfully and deliberately. The AHA is pleased that the options paper proposes to implement the program incrementally, reward both quality improvement and quality attainment, fund the pool through adjustments to the base MS-DRG amount, which excludes add-on payments (indirect medical education (IME), disproportionate share hospital (DSH), low-volume adjustment payments and outlier payments), and create demonstration projects to test VBP models for critical access and small hospitals.

VBP purchasing should be done in a budget-neutral manner.

We strongly believe that VBP should be implemented in a budget-neutral manner and that both high-performing and improving hospitals should be able to receive bonus payments as a reward for their achievements. As currently structured, high-performing hospitals would be "rewarded" by winning back only the portion of the withheld payment to which they were already scheduled to receive. The remaining 75 percent of hospitals would receive either a portion or none of the money withheld from their payments. A budget-neutral provision would redistribute payments from low performers to high performers. We believe it is important that at least a portion of hospitals have the potential to receive increased funding from Medicare under this provision.

The incentive pool should be no larger than 1 percent.

The AHA recommends that no more than 1 percent of hospital payment be used to reward performance. The size of the reduction proposed is too large for a program that is untested and not proven to achieve better patient outcomes. It is much larger than the 1 or 2 percent recommended by MedPAC, and the 0.5 to 2.0 percent phase in recommended in the *Baucus-Grassley Medicare Value Based Purchasing Act of 2005*. Hospital quality scores have continuously increased under the pay-for-reporting program that publicly reports hospital performance. Rather than the large withhold suggested, we believe an incentive of 1 percent is sufficient enough to help align quality and payment and to encourage hospitals to adhere to evidence-based care.

Measures should be selected through a consensus-based process.

The SFC proposal calls for measures to be selected from those used in the current Medicare pay-for-reporting program, including measures for heart attack, heart failure, pneumonia and surgical care, and measures assessing patients' experience of care. The Secretary of the Department of Health and Human Services (HHS) would have the ability to expand the list after the first year. We believe selection of the measures is critical to the success of a VBP program. It is crucial they be developed through an open, transparent and consensus-based process. As written, it is unclear whether only measures endorsed by the National Quality Forum (NQF) and adopted by the Hospital Quality Alliance (HQA) would be included. We urge Congress to enumerate that only NQF-endorsed and HQA-approved measures be included in any VBP program.

Only a subset of MS-DRGs should be subject to the withhold pool.

Only the MS-DRGs related to the quality measures – rather than all MS-DRGs – should be subject to the withhold pool. It is excessive to reduce payments to all MS-DRGs based on a hospital's performance on only a subset of MS-DRGs.

Multiple condition-specific composite scores should be used.

The proposal recommends using a single composite performance score to determine whether a hospital meets the overall performance standard. This approach will make it difficult for hospitals to determine areas where they need to improve and to direct their quality improvement efforts accordingly. The AHA supports using multiple condition-specific composite scores to evaluate hospital performance. This would allow hospitals to receive an incentive payment for clinical areas where they perform well, while penalizing them in clinical areas where they are low performers. This will also protect those hospitals with a low volume of patients in certain services and minimize the impact of potentially arbitrary weighting policies.

BUNDLED PAYMENT

The SFC proposal would establish a post-acute care (PAC) bundling policy to encourage greater coordination of care among acute and PAC providers. Starting in FY 2015, acute inpatient hospital services and PAC services – including home health, skilled nursing,

inpatient rehabilitation and long-term care hospital services – occurring or initiated within 30 days of the acute hospital discharge would be paid through a bundled Medicare payment. Physician services would be excluded from the bundle. The bundled payment would be the average Medicare amount for the inpatient MS-DRG plus the average Medicare post-acute care costs of treating patients in that MS-DRG, plus the cost of expected or planned readmissions within the 30 day-post acute timeframe, minus an amount for expected efficiencies to be gained from improved care coordination. Bundling would be implemented through a three-stage process, beginning with a subset of MS-DRGs in FY 2015 and ending with all MS-DRGs in FY 2019.

The AHA supports efforts to bring providers together to coordinate care, and bundling Medicare payments may ultimately be a way to encourage the delivery of efficient and effective care. This is an extremely complex issue, however, and has not been tried or implemented broadly in the public or private sector. We strongly recommend careful design and testing of any bundling provision prior to widespread implementation. While we commend the SFC proposal for phasing-in its implementation over a number of years, we believe that an incremental approach that tests different models of bundling to determine what works and what does not is critical before broad adoption.

Bundling should be explored through voluntary demonstration projects.

While some hospitals are organized in ways that facilitate bundling payments, most are not clinically integrated to implement such a policy. It is essential to provide hospitals and other providers with the tools and infrastructure necessary for coordinating care and managing risk. Changes in law and regulation, discussed later in this document, are necessary elements to the successful implementation of bundling. Without such changes, bundling payment will be difficult to achieve.

We strongly urge the Committee to consider using demonstration projects to develop and explore the many design elements of this complex payment approach before implementing it across all providers. Specifically, we recommend that hospitals be allowed to participate in bundling demonstrations on a voluntary basis. Various approaches should be allowed and tested – such as hospital-physician, hospital-PAC, hospital-physician-PAC, and PAC-only bundling. Such incremental approaches are warranted to ensure that changes do not result in inequities or other harmful unintended consequences for providers and patients. Additionally, bundling should be limited to high-cost, high-volume services where better patient management across care settings is needed.

Physician services should be included in the bundle.

The SFC's proposal would bundle hospital and PAC services, but would exclude physician services. Physicians are critical players in the delivery of health care services: they decide whether or not to admit a patient to the hospital; they determine which services are needed to treat a patient; and they order all follow-up care. Without the inclusion of physicians in the payment bundle, we will not have the aligned incentives that are essential to achieving better care coordination, quality and efficiency.

Legal and regulatory barriers to care coordination should be removed.

A number of legal and regulatory barriers would need to be removed to allow greater care coordination and management of patients by both hospitals and physicians. Under the SFC proposal, the Centers for Medicare & Medicaid Services (CMS) is directed to waive certain laws to ensure patients receive appropriate PAC services and that access to care is maintained. CMS also would examine payment rules in the existing post-acute payment system to determine if modifications are needed to allow proper coordination and care management of patients. We applaud the SFC for including these elements in its proposal because providers' ability to respond to bundling payment incentives currently is significantly hampered by multiple laws and regulations. In addition to the antitrust laws, four federal statutes have a significant impact on hospitals' ability to form financial relationships with physicians: the *Ethics in Patient Referrals Act*, also known as the "Stark" law; the anti-kickback statute; the Civil Money Penalty (CMP) law; and the tax-exemption provisions of the Internal Revenue Code. These regulations severely limit a hospital's ability to respond to the incentives of a bundled payment system.

Existing regulations also inhibit care coordination and would need to be reformed or withdrawn to achieve the goals of bundling. For example, today's requirement that hospitals provide a list of all local home health providers to patients at the point of discharge would need to be eliminated. In a new bundled payment system, hospitals, working in collaboration with physicians and post-acute providers, will need the ability to choose the post-acute setting that is appropriate for patient care. The inpatient rehabilitation facility "60% Rule," long-term care hospital "25% Rule" and the skilled nursing facility "3-day Inpatient Stay Rule" would also inappropriately hamper care management and should be rescinded under a bundled payment system.

Additional data and information are needed.

Under a bundled payment system, new quality and outcome measures would be necessary to ensure that appropriate care is provided throughout the entire episode of care. In addition, changes to existing fee-for-service payment methods would be necessary to provide Medicare payment to PAC providers after the 30-day bundled timeframe has ended. Finally, at this time, only CMS and certain researchers have an ability to conduct analyses of patient-care utilization and cost across multiple provider settings. To ensure that policies are appropriate and their implementation is transparent, Congress should require that CMS release claims and other necessary data for hospitals and others to analyze bundled care. Doing so would lead hospitals and others to a greater understanding of the services and costs involved in an episode of care, which would in turn lead to improvements in the provision of care.

READMISSIONS

The SFC options paper would establish a readmission policy, in conjunction with the PAC bundling policy, to encourage greater coordination among acute and post-acute care

providers. Starting in FY 2010, CMS would calculate national and hospital-specific data on the readmission rates of PPS hospitals for eight conditions with the highest volume and the highest rates of readmissions. Selection of the initial eight conditions would be left to the discretion of the Secretary and could be updated over time. Starting in FY 2013, hospitals with readmission rates above the 75th percentile for selected conditions, based on a hospital's prior year performance, would be subject to a 20 percent payment withhold for the selected MS-DRGs. Money from this withhold would be returned to a hospital only if a new patient assigned to that relevant MS-DRG in FY 2013 were not readmitted to a hospital within 30 days for a "preventable" readmission. The readmissions policy would be phased out as the bundling policy was adopted.

Preventing readmissions is a complex, system-wide problem that involves hospitals, physicians and other providers who manage patients' care, as well as patients and their families. Hospital leaders and clinicians who care for patients recognize that some readmissions can be prevented. But there are a number of factors beyond the hospital's control that affect whether a patient is readmitted, including the natural course of the disease, the limited availability of post-acute and ambulatory health care services, high levels of poverty among some hospitals' patients, and a lack of community-based social services. These factors substantially affect a hospital's performance on readmission measures. If these factors are not accounted for, they will lead to payment penalties, inequities and other serious consequences – intended and unintended – for hospitals, particularly safety-net hospitals.

Focus on certain unplanned but related readmissions.

Public policies seeking to reduce readmissions should focus exclusively on certain types of unplanned readmissions that are related to the initial admission for which there are evidence-based approaches or actions that hospitals can take to prevent the occurrence of the readmission. Readmissions that are planned as part of the recommended course of treatment or unrelated to the original admission should be excluded. Readmissions that can be reasonably "paired" with an initial admission would be a good place to start, such as an orthopedic surgery followed by readmission for a blood clotting disorder. Additionally, the SFC could consider incorporating measures of quality into the readmissions policy such that only hospitals with both high readmission rates and low quality performance scores are penalized. This would allow high-performing hospitals with outstanding quality not to be penalized for treating complex patients who might have higher rates of readmission given their disease types, comorbidities or other social conditions.

The AHA commends the SFC for acknowledging that certain conditions should be excluded. These conditions should be identified as preventable using currently available administrative data. In addition to cancer, burn and trauma care, and scheduled surgeries, which the SFC option paper identified as not preventable, there are other types of readmissions that also are not preventable and should be explicitly excluded from a

readmission policy, including psychoses, maternity and neonatal, and end-stage renal disease.

Reduce payment only after a patient has been readmitted.

We are concerned about the SFC's proposal to withhold 20 percent of certain hospitals' Medicare payments for certain MS-DRGs and then pay back the withheld funds if patients are not readmitted within 30 days. This excessive, prospective reduction in payment would place a significant financial strain on providers. It is particularly problematic for small and rural hospitals that have limited cash flow. The AHA recommends that hospital payments be reduced only *after* a readmission occurs. Such a policy could be implemented in a manner similar to the CMS' inpatient PPS post-acute care transfer policy. Additionally, the withhold amount should be smaller than 20 percent. Given that the readmission policy would apply to high-volume MS-DRGs, withholding such a high percentage of payments would create significant "cash-on-hand" problems and other financial difficulties. This is particularly problematic for small and rural hospitals that have limited cash flow. A smaller amount, such as 5 percent, would create the same incentives to reduce readmissions.

Focus on readmissions within seven days of hospitalization.

Applying the policy to readmissions within 30 days of hospital discharge is not appropriate. The longer the length of time after a patient's discharge, the more likely it becomes that the readmission is not related to the initial admission. It also makes it more and more unlikely that that readmission could have been reasonably prevented by the hospital. A timeframe of seven days is more appropriate for a readmission policy that affects hospital payment.

Make Medicare claims data available.

At this time, only CMS and certain researchers have the ability to conduct readmission analyses with Medicare claims data. Hospitals cannot calculate complete readmission rates because they do not have data on readmissions to other hospitals, and policymakers cannot calculate readmission rates because access to patient-identifiable claims data is restricted. Given that readmission rates are a central aspect of the SFC's proposal, Congress should require that CMS release patient-identifiable claims data to hospitals and others, in an appropriate manner, so they can duplicate the hospital readmission rates calculated by CMS. This is critical to ensuring that the readmissions policy is fully transparent.

ACCOUNTABLE CARE ORGANIZATIONS (ACOs)

Beginning in FY 2012, groups of qualifying providers – such as individual physician practices, physician group practices, hospital-physician joint ventures and hospitals employing physicians – would be allowed to voluntarily form ACOs and have the opportunity to share in the cost savings they achieve for the Medicare program.

ACOs offer an opportunity to improve integration of inpatient and outpatient care and promote joint accountability for care delivery across providers and across time. Especially important is the working relationship between hospitals and physicians, as well as other post-acute and community-based agencies. The AHA supported a similar concept of care delivery in the early 1990s called Community Care Networks and we believe there should be opportunities to test the ACO approach today. However, ACOs will not work in all areas of the country, as defined by the SFC. For example, most rural areas would not be able to meet the minimum 5,000 beneficiary requirement. ACOs also will require regulatory and/or legislative changes to eliminate or modernize the several federal laws that impede hospitals and physicians working together and to utilize incentives to improve the quality of care and increase efficiency.

REDISTRIBUTION OF UNUSED GRADUATE MEDICAL EDUCATION (GME) SLOTS

The SFC draft proposes to redistribute unused GME slots to increase access to primary care and general surgery. Specifically, it proposes to reallocate 80 percent of slots unused for three years, and allows hospitals to request up to 50 new slots. Seventy-five percent of new slots would be designated for primary care or general surgery for five years. Slots would be redistributed based on a set of criteria, such as whether the receiving hospital is in a health professional shortage area.

We applaud efforts to expand the number of physicians to improve access and expand health coverage. We support the SFC proposal to redistribute unused residency slots. According to recent data from the Association of American Medical Colleges (AAMC), hospitals currently are training approximately 6,900 residents over their resident caps. Given that there are approximately 1,700 residency slots that have not been used for the past three years, we are pleased that these unused slots will be reallocated to hospitals that are already training physicians. This will help address a portion of the current need. However, given the enhanced need for resident slots now, coupled with the projected shortage of physicians in the future, the AHA recommends increasing the number of Medicare-supported training positions for medical residents by 15,000 slots.

PHYSICIAN SELF-REFERRAL

The SFC paper proposes that the current “whole hospital” and rural exceptions be repealed under the *Ethics in Patient Referrals Act*, better known as the “Stark” law. They would be replaced by an exception for physician-owned hospitals with a Medicare provider number as of July 1, 2009. These hospitals would be “grandfathered” and allowed to continue to self-refer, subject to certain conditions. This new grandfathering exception includes several conditions for those physician-owned hospitals such as:

- Ethical investment practice rules to ensure bona fide investment and proportional returns on investment;
- Disclosure of physician ownership interests in hospitals to patients at the point of referral and again at the earliest point of an admission, to the public through notices on the hospital's Web site, and in reporting to CMS, which is charged with providing ownership information on its Web site;
- Patient safety requirements to ensure that such hospitals are capable of responding appropriately to complications or emergencies and safely transferring patients who need care beyond their ability, as well as patient disclosure at admission if the hospital does not have 24-hour/7-day onsite physician coverage; and
- Required approval by HHS of any increase in the number of operating rooms, procedure rooms and beds, as well restrictions on growth overall and conditions that must be met.

We applaud the SFC for the inclusion of this important provision. The proliferation of physician ownership of hospitals is stimulated by opportunities for physicians to earn additional income and gain greater control over their operating environment. However, the effect on health care delivery and costs to communities can be devastating. The AHA supports a ban on physician self-referral to limited-service hospitals, with limited exceptions for existing facilities that meet strict investment and disclosure rules.

SUSTAINABLE GROWTH RATE (SGR)

The SFC draft proposes two options to fix the SGR problem under the physician fee schedule (PFS). The first option would provide a 1 percent update in calendar years (CY) 2010 and 2011, a zero percent update in CY 2012, and then revert back to current law for the update in CY 2013 and beyond. The second option would implement the same schedule of updates for CYs 2010-2012, but would place a floor of negative 3 percent in effect in CY 2013. Beginning in CY 2014, the PFS update for localities with two-year average fee-for-service growth rates at or greater than 110 percent of the national average would have a negative 6 percent floor. We support fixing the PFS by providing physicians with a positive update in CYs 2010 and 2011, and believe that a permanent fix to the SGR is needed.

CLINICAL INTEGRATION

The ability of doctors and hospitals to work together and clinically integrate is an important element of delivery system reform. As mentioned, we believe it is critical that current barriers to care coordination be removed or modernized so that caregivers can work together more effectively to improve patient care. Below is an explanation of the laws and regulations that hamper the ability of physicians and hospitals to respond to the payment incentives the SFC has outlined in its options paper, especially those around VBP, readmissions and bundling:

1. **Federal Antitrust Laws** (Sherman, Clayton, and FTC Acts) prohibit joint action (with potential criminal penalties) by hospitals and physicians unless they are sufficiently clinically or financially integrated. The current lack of guidance on clinical integration creates uncertainty, making it difficult for a hospital and doctors to collaborate to improve care coordination across settings. The federal antitrust agencies (the Department of Justice (DOJ) Antitrust Division and Federal Trade Commission (FTC)) could make a significant contribution to furthering clinical integration by working with the hospital field to provide guidance to providers, who are eager to undertake clinical integration programs – guidance that providers could readily understand and use. The success of the FTC’s earlier *Statements of Antitrust Enforcement Policy in Health Care* in addressing providers’ concerns about the vagaries of the antitrust laws suggests that a similar effort more focused on clinical integration would be of substantial benefit to providers as they explore innovative approaches to working together to improve quality and lower the cost of health care.
2. **Medicare’s Civil Money Penalty (CMP) Law** prohibits hospitals from paying physicians for reducing or limiting services to a Medicare or Medicaid beneficiary. Enacted soon after Medicare adopted the prospective payment system, the CMP law was an attempt to ease concerns that the new system might lead hospitals to pay physicians to reduce services. In 1999, the HHS Office of the Inspector General (OIG) surprised the hospital field by issuing a *Special Advisory Bulletin* interpreting the statute to prohibit any payment that has the effect of reducing or limiting services without regard to whether they were medically necessary or appropriate. This interpretation is obstructing care improvement initiatives, especially incentives for physicians to bring their practices in line with evidence-based, clinical protocols.
3. **The Ethics in Patient Referrals Act (Stark law)** limits financial relationships between hospitals and physicians. The current law and regulations, chiefly in non-ownership situations, impede the use of financial incentives as part of care improvement initiatives and clinical integration activities. The Stark law prohibits a physician, or his or her immediate family member, from making referrals for certain designated health services paid for by Medicare, including inpatient or outpatient hospital services, to an entity with which the physician or immediate family member has a financial relationship (self-referral), unless an exception applies.

The physician is subject to a civil money penalty if he or she knowingly makes a noncompliant referral, as is the entity – a hospital, for example – that knowingly makes a claim for services provided pursuant to a noncompliant referral. In addition, a hospital is liable for any reimbursement related to services ordered by the self-referring physician, regardless of whether the hospital knew the referral was noncompliant. The statute also creates exceptions under which arrangements that otherwise would be prohibited may go forward. These include a general exception for payments that are fair market value, another for personal service arrangements and another for

employment, both of which also include a fair market value criterion. In the new world of health care delivery, however, where payments are increasingly conditioned on outcomes, measuring a fair market rate for services rendered is ill-suited to aligning hospital and physician interests.

4. ***Medicare's Antikickback Law*** prohibits any payment or reward to induce patient referrals. Current agency guidance inhibits the use of savings or performance incentives related to quality or safety of care. The antikickback statute prohibits, among other things, knowingly or willfully offering or accepting any benefit or "remuneration" in exchange for, or to induce the referral of, patients for services, or the purchase, lease or order of any good, facility, service or item paid for by Medicare, Medicaid and most other federally funded health care programs. These carry both civil and criminal penalties. The breadth of the statute places any financial arrangement under scrutiny. While the OIG has authority to issue advisory opinions providing advance clearance for an arrangement, only the person making the request is protected and the opinion is limited to the precise facts provided in the request. Like the Stark law, the antikickback statute inhibits the use of incentives to implement the clinical protocols and practices that are needed to improve quality and efficiency.
5. ***The Internal Revenue Service's (IRS) Tax-Exempt Laws*** prohibit private benefit or inurement by tax-exempt hospitals to physicians. Current rules limit performance-related payments to physicians. One of the fundamental conditions of tax exemption is that the organization's assets may not "inure to the benefit of any private shareholders or individuals." The standard is strictest for those who are board members or in a position to control or significantly influence the decisions of the organization, sometimes referred to as "insiders." The IRS no longer takes the position that all physicians on a hospital's medical staff are insiders and instead uses a case-by-case, "facts and circumstances" approach. Nevertheless, relationships with physicians are given particular scrutiny and, under certain circumstances, incentive compensation can be seen as constituting inurement of the hospital's net earnings to private individuals.

By design or effect, each of these statutes creates a tension around hospital and physician financial relationships. Under the Stark and antikickback laws, payments from hospitals to physicians are almost always suspect – presumed by policymakers to be a means to induce referrals, interfere with clinical decisions, or increase payments from federal health care programs. Under the CMP law, the concern is that hospitals might encourage doctors to limit or reduce services provided to program beneficiaries by offering a share of the resulting financial gains. Under the Internal Revenue Code, the suspicion is that payments to physicians will be for the private benefit of the physicians and not to advance the charitable purpose of the hospital. Under these statutes, the litmus test of a payment's legality is typically whether it is "fair market value" for a service provided by the physician, a standard that is not well-suited when the emphasis is more on achieving outcomes than payment for work.

We believe that the impediments raised by these laws and policies need to be addressed because providers will not be able to respond sufficiently without the ability to utilize performance incentives to change care delivery so that it is both more effective and more efficient. In some instances, doing so could be achieved by issuing more direct guidance, similar to what hospitals are seeking from the antitrust agencies; in other instances, legislation or other regulatory policy changes are needed to effectively remove the impediment. The ultimate objective is to achieve complementary guidance under these laws so that they all enable the same hospital-physician activity, even while assessing the issues from the perspective of each law. More specifically:

- The SFC should direct the DOJ to take the lead in issuing guidance, similar to that found in the *Statements in Antitrust Enforcement Policy*, that is in accord with the *Guidance for Clinical Integration*, a working paper prepared for AHA by antitrust experts and provided to DOJ in 2008, and at an FTC workshop on May 29, 2008. That process could start with a request from Congress for an immediate briefing by DOJ's Antitrust Division on ways to implement that guidance.
- The SFC should enact a safe harbor under the antikickback law to allow incentive payments and shared-savings programs in relationships between hospitals and physicians. The safe harbor should strike a balance between protection for the Medicare program and flexibility for hospitals of different sizes, locations and resources to work with physicians to structure arrangements to meet the quality, patient safety and efficiency goals that public policy demands. The AHA and others developed such a proposal in response to a request for input from CMS, which was then provided on February 17, 2009 to both CMS and the OIG. The proposed framework for developing implementing regulations should:
 - ✓ Establish only those requirements that are essential or material to reasonably ensure that the arrangement is not to induce referrals.
 - ✓ Establish accountabilities for hospitals to demonstrate goals for improving quality and efficiency, but not regulate the specific means by which they are achieved.
 - ✓ Use the preamble to any rule to provide non-exclusive illustrations of potential ways to demonstrate compliance with elements of the exception. Guidance on ways to comply with the exception is welcome, but writing it into the regulation creates mandates that are significantly limiting and can quickly become out of date.
- Congress should remove compensation arrangements, including incentives and shared savings programs, from coverage under the Stark law; they are and would continue to be subject to the Antikickback and civil monetary penalty prohibitions on payments to induce referrals.

- The SFC should instruct CMS and the OIG to interpret the Civil Money Penalty Law prohibition on inducements to physicians to reduce or withhold services as meaning only when the services are medically necessary. Alternatively, a simple word change in the Civil Money Penalty law to insert the term “medically necessary” into the prohibition also would be effective.
- The SFC should instruct the IRS to ensure that its rules regarding private inurement are consistent in allowing incentive payments and shared-savings programs when they meet the requirements of the antikickback safe harbor.

ADMINISTRATIVE SIMPLIFICATION

In 2007, the U.S. Congressional Research Service estimated that the administrative costs of private insurance and government programs were about \$465 billion a year. This figure does not include the administrative costs borne by health care providers to comply with these requirements. Most experts estimate that about a quarter of total hospital spending and a little more than a quarter of physician office revenue is spent on complying with administrative requirements. And, increasingly complex administrative requirements cause great confusion for patients and their families, who often find that a service is not covered by their insurance or that their out-of-pocket liability is greater than expected. A major key to reducing administrative cost and confusion is limiting the variability and complexity of both public and private health plans by standardizing plan design and benefits, plan notifications, claims submission and adjudication, and appeals.

The AHA recommends that the SFC and Congress require the adoption of a standardized framework and terminology within which all health plans (whether subject to federal and state or just federal regulation) would be required to describe their plans, the benefits covered, the conditions for coverage, and the cost-sharing required (i.e., deductibles, copayments, coinsurance, balance billing), including any differences related to the use of in-network or out-of-network providers. Such a requirement would allow plans to continue to develop customized plans for different purchasers, as long as their descriptive information adheres to the standard framework and terminology so that consumers can more easily compare health plans and better understand their coverage and its limitations.

Hospitals also recommend expanding the scope of the administrative simplification provisions of the *Health Insurance Portability and Accountability Act* (HIPAA) statute, specifically:

- Establish common rules for claims involving coordination of benefits to increase the timeliness and accuracy of processing those claims.
- Expand the transaction standards to require that health plans fully utilize the information codes in the uniform bill.

- Prohibit administrative denials for otherwise covered and medically necessary services unless there is a documented pattern of repeated provider abuse.
- Establish requirements to standardize Explanations of Benefits (EOBs)
- Improve remittance transaction standards to standardize and better define common terms and timeframes so that providers will have accurate and timely information about the disposition of individual claims and specific adjustments made to plan payments for billed services.
- Make modifications to ensure that claims are paid on a timely basis.
- Establish a more standardized and equitable process for auditing and resolving claims.

Finally, hospitals recommend that the SFC standardize the collection and reporting of clinical information for quality measures. The ever-increasing burden to collect, analyze and submit vast amounts of patient care data associated with quality and patient safety, along with the lack of consistency in public and private payer requirements, has made it more difficult for providers to spend their time treating patients. All payers should adhere to common definitions for data elements and standard practices around data collection, submission and frequency of reporting.

The AHA will continue to work with the SFC and its staff to strengthen the ideas presented in the options paper. We are steadfast in our support of delivery system reform and look forward to working with the Committee and its staff as Congress moves forward with reform legislation.