

Hospitals & Health Systems Rx

Table of Contents

Hidden Gems of PPACA: New Rules for Physician- Owned Hospitals <i>Andrew Demetriou, Esq.</i>	1
PPACA Section 3025: The Hospital Readmissions Reduction Program <i>Keith Mauriello, Esq.</i> <i>Neil Hoffman, Esq., PhD</i>	5
The Required Hospital Standard Charge Publication That You Probably Missed <i>Clinton Mikel, Esq.</i> <i>Neda Mirafzali, Esq.</i>	9
Religion and Health Insurance Exchanges <i>Sarah Swank, Esq.</i>	13
Reporting and Returning Overpayments: Complications, Risks, and Headaches Under PPACA <i>James Dietz, Esq.</i>	14



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—from a declaration of the American Bar Association

Hidden Gems of PPACA: New Rules for Physician- Owned Hospitals

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Among the lesser-noted reforms in the Patient Protection and Affordable Care Act of 2010 (PPACA) was a substantial modification in the terms of the “whole hospital” exception from the federal physician self-referral law, known as the Stark Law,¹ which has served as a basis for physician ownership of certain hospital facilities for nearly two decades. This change has profound implications for hospitals with physician owners.

The Stark Law generally prohibits physicians, and entities receiving referrals from physicians, from billing federal health programs for referrals involving designated health services (DHS) if the physician has an ownership interest in, or compensation arrangement with, the entity to which the referral is made.² An exception, for investments of physicians in a whole hospital (as opposed to a department or treatment unit), was included in the 1993 amendments expanding the coverage of the Stark Law to include inpatient and outpatient hospital services.³ The ostensible reason for this exception was that the referrals of any individual physician may not materially affect the financial results of the hospital (and the value of the physician’s investment), so long as the economic returns to the physician were not related to the value or volume of referrals made by the physician. This exception was controversial and has been criticized by tax-exempt and investor-owned hospitals and hospital systems, who have contended that the permitted economic relationship was not so attenuated as to not induce referrals to hospitals in which the physicians hold interests and that the exception largely fostered the creation of specialty physician-owned hospitals that provided only lucrative services, which in turn were directed away from general acute care hospitals by the physician-owners.⁴

The provisions of PPACA Section 6001 amended the whole hospital exception to: (1) freeze ownership by referring physicians of hospitals or entities that own hospitals at the level that existed on March 23, 2010; (2) limit the expansion of hospital facilities that are owned by referring physicians; (3) require hospitals to include provisions relating to disclosure of physician ownership in their provider or similar agreement with referring physicians; and (4) impose new requirements on hospitals and physician owners with respect to disclosure of physician ownership of hospitals to patients. The U.S. Department of Health and Human Services (HHS) promulgated final regulations (Regulations) to implement the PPACA provisions on November 24, 2010,⁵ and the preamble to the Regulations (Preamble) provides useful insight as to the government’s interpretation of the whole hospital exception going forward, through discus-

sion of comments made on the draft of the Regulations. Compliance with the new law and the Regulations became mandatory on September 23, 2011, except where an earlier date was specified, e.g., the requirement that physician ownership in a hospital must have existed as of March 23, 2010, or not later than December 31, 2010, in the case of a physician-owned facility that was under development but not licensed or did not have a provider number as of March 23, 2010.

Implications of the PPACA Amendments

Physician Ownership Limitation

The changes to the whole hospital exception have several implications for physician-owned hospitals. First, and most important, it is now necessary to determine “the percentage of the total value of ownership or investment interest” held in the hospital, or any entity that owns the hospital, by physician owners as of March 23, 2010. Compliance with this requirement implies that a physician-owned hospital must employ a reasonable methodology to determine physician ownership as it existed on March 23, 2010.

Changes in the identity of the physician owners or the number of individual physician owners will not violate the law, so long as the aggregate level of physician investment remains constant or declines.⁶

A key problem with the law is that it is not clear what indicia of physician ownership is fixed as of March 23, 2010, due to the imprecise language of PPACA Section 6001.⁷ The relevant provision states: “[t]he percentage of the total *value* of the ownership or investment interests held in the hospital [by physicians] . . . does not exceed such *percentage* as of the date of enactment of this subsection [i.e., March 23, 2010].”⁸ At a simplistic level, assuming a single class of stock, it would seem that the percentage of stock held by referring physicians should be the applicable measurement, and that so long as that level of percentage ownership is maintained or decreases, the hospital should be in compliance with the law. In response to a comment proposing that the Regulations adopt a standard based on percentage of outstanding stock held by physicians, HHS rejected that interpretation and stated the “[t]he plain language of the statute refers to the *value* of the investment interests, not the number of shares held by physicians.”⁹ This statement, which was not actually responsive to the comment, could be read as suggesting that there is a percentage of the “value” of the hospital attributed to the physician ownership that is different from the percentage of stock or other ownership interests held by physicians and would need to be established as of March 23, 2010, and that the *value* of the physician interest so derived could not be exceeded in the future.

This interpretation is problematic and it is not clear that HHS’ expressed view is consistent with a reasonable reading of the law. In another part of the Preamble, HHS states: “we are clarifying that a physician-owned hospital may add or increase the number of physician owners or investors, or replace physician owners or investors, so long as the aggregate percentage of physician owner-

ship or investment does not increase.”¹⁰ If in fact the purpose of the language of Section 1877(i)(1)(D) is to cap the absolute value of the physician interest in a hospital, that would be a highly troublesome standard to enforce, in that value is changeable and difficult to assess in real time. In addition, such an interpretation would create the untenable situation in which referrals by the physician owners would be permitted or prohibited based on swings in value over which neither they nor the hospital could exert meaningful control.

Perhaps the point of the HHS response is to distinguish a percentage ownership of the enterprise that can be manipulated—e.g., by dilution of the number of shares held by physicians—from a value-based percentage, in which case monitoring the relative level of physician ownership compared to other investors, rather than its absolute value, should suffice. Pending further clarification, however, the authors cannot be certain how this cap will be applied.

A further problem is that neither PPACA nor the Regulations define “aggregate level of physician ownership” in a manner that takes into account unexercised rights to purchase shares or other derivative securities held by non-referring physicians. Reliance on measurements of percentage ownership based, for example, on the rules of the U.S. Securities and Exchange Commission,¹¹ may or may not be consistent with the calculations required for the Stark Law. The regulations under the Stark Law treat any options, warrants, or similar securities held by a physician as part of an ownership interest,¹² unless they were issued as compensation, in which case they are treated as part of a compensation arrangement, rather than an ownership interest, until exercised. There is no rule governing similar interests held by shareholders who are not referring physicians, as until now the extent of their holdings was not relevant.

A related issue is that PPACA requires that a hospital establish that current and future physician investment interests are bona fide and prescribes a seven-part test for this purpose.¹³ The elements prescribed are as follows: (1) the percentage ownership test mentioned above; (2) any ownership or investment interests may not be offered on more-favorable terms than the terms offered to a person who is not a physician investor or owner; (3) the hospital (or any owner or investor in the hospital) must not provide loans or financing for any investment in the hospital by a physician owner or investor; (4) the hospital (or any owner or investor in the hospital) must not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital; (5) ownership or investment returns must be distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital; (6) physician owners must not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or

investors in the hospital or located near the premises of the hospital; and (7) the hospital must not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more-favorable terms than the terms offered to any individual who is not a physician owner or investor.

This requirement implies that a physician-owned hospital should review any arrangements under which shares held by physicians were acquired as well as any agreements that may be implicated by the criteria above, such as loan arrangements with physicians or agreements with respect to hospital property.

The statute also creates an obligation to track ownership of its stock by referring physicians, both as of March 23, 2010, and thereafter. This is necessary both to assess compliance with the bona fide ownership test above as well as for purposes of annual reporting to the HHS Secretary in accordance with new Section 1877(i)(1)(C)(i). The Preamble notes that the agency has not proposed procedures for this reporting requirement, but pledged to do so either by rule or issuance of guidance.¹⁴

It would be prudent for a hospital with physician owners to take at least two steps toward the determination of referring physician ownership to assess compliance with the law. The first would be to require each member of the medical staff of the hospital to indicate whether they, any member of their immediate family, or any entity they own or control owns shares of stock or other interests in the hospital. As noted below, this will be necessary to comply with conflict of interest and disclosure obligations of both the hospital and each physician that were enacted by PPACA. Second, hospital management should review records of ownership, including stock registers, and if applicable statements of a corporate transfer agent, against lists of its medical staff. This latter step would serve as an independent check for the benefit of the hospital as well as a means of evaluating physician compliance with the disclosure requirement.

A problem could arise in the event that physician ownership in the hospital is indirect, and thus not apparent from ownership records. Under the indirect ownership rules,¹⁵ the entity providing DHS must have actual knowledge, or act in reckless disregard of deliberate ignorance of, the fact that the physician or an immediate family member has an ownership or investment interest in the entity for a violation to exist. Unfortunately this provision does not address the situation in which a physician acquires and then conceals a direct, rather than an indirect interest, and it does not strictly apply to situations such as ownership in street name of publicly traded securities, where the nominal shareholder is merely a custodian, and not actually an owner of the securities. An indirect interest subject to the Stark Law can exist in a situation in which the hospital is aware of the general indirect relationship, but may not be aware of all of links that form the unbroken ownership chain,¹⁶ and this implies a diligence obligation on the part of the hospital to determine whether current medical staff members may possess ownership interests that are not apparent.

Facility Cap

In addition to ownership limitations, PPACA also imposes a cap on facilities operated by physician-owned hospitals and hospital-holding entities. Absent consent from the HHS Secretary, under procedures which have not yet been specified, a physician-owned hospital may not have a greater number of operating rooms, procedure rooms, or beds than existed under its license as of March 23, 2010.¹⁷ This provision was controversial because, in many states only beds, as opposed to operating or procedure rooms, are actually licensed. In responding to comments on this point, HHS indicated that the limitation applies to the number of operating rooms and procedure rooms that existed on March 23, 2010, whether or not such rooms are licensed under applicable state law.¹⁸ The agency indicated that the law was intended to enforce only a numerical cap rather than a freeze on the actual rooms and licensed beds in existence, thus a hospital could relocate, make modifications to the use of, or retire licensed beds or rooms, so long as it stayed within the overall cap.¹⁹

For this purpose, the term “procedure rooms” is defined to include rooms in which catheterization, angiographies, angiograms, and endoscopies are performed, but generally excludes emergency rooms (except for areas in an emergency room that provide those services).²⁰ While HHS has authority to include procedure rooms that are used to provide other services, and has invited comments on whether it should include rooms in which services such as CT or PET scans are performed, thus far it intends to stick to the specification in the statute.²¹

A limited exception from the cap on facilities applies to a hospital: (1) located in a county that has experienced a population growth of at least 150% of the percentage growth in the population of the state in which the hospital is located; (2) whose annual percentage of inpatient admissions covered by the Medicaid program exceeds the average for all hospitals located within the county in which the hospital is located; (3) that does not discriminate against beneficiaries of federal healthcare programs nor permit its physicians to discriminate against them; (4) that is located in a state in which the average bed capacity is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the state in which the hospital is located.²² This exception is limited to an increase of 100% more than the number of beds and procedure rooms at the “main campus” of the hospital in existence on March 23, 2010, and is available for only two years at a time, subject to renewal at HHS’ discretion.

Conflict-of-Interest Disclosures

The law now requires that: (1) a physician-owned hospital make annual reports to HHS of the identify of each physician owner or investor or any other owners or investors of the hospital as well as the nature and extent; (2) the hospital maintain procedures in place to require that any referring physician discloses to patients that they have an ownership or investment interest in the

hospital; (3) that the hospital not condition physician ownership or investment interests on the referral of patients to the hospital; and (4) that the hospital disclose the fact that it is partially owned or invested in by physicians on its website and in any public advertising.

HHS intends that hospitals require, as a condition of staff privileges, that each physician provide written disclosure of their ownership or investment interest in the hospital to all patients the physician refers to the hospital. This disclosure must be required by a time that permits the patient to make a meaningful decision regarding the receipt of care.²³ The government views this as an adjunct to existing requirements that a physician-owned hospital provide notice to patients that it is physician owned and offer to provide a list of physician owners upon request and that physicians make similar disclosures.²⁴ In response to a comment raising the issues of whether the burden should be placed on the hospital as opposed to directly on the physicians as well as concerns that physician non-compliance would jeopardize the hospital under the Stark Law, HHS relied on the statutory command that the hospital maintain the applicable procedures and stated:

A physician's failure to fully comply with such an agreement [the disclosures required for staff privileges] is a disciplinary matter for the hospital to resolve in accordance with the medical staff bylaws and would not necessarily result in a violation of the physician self-referral law. As noted above, a similar requirement already appears in our provider agreement regulations at § 489.20(u)(2).²⁵

Nonetheless, this implies that the hospital may well have a duty to discover physician non-compliance and then address the matter through discipline to assure that it has not contributed to a Stark Law violation.

The requirement imposed by Section 1877(i)(1)(C)(iii), that the hospital not condition physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise-generating business for the hospital, is consistent with well-established principles under the anti-kickback laws and should be viewed as within good compliance practices.

Finally, the requirements for disclosure on websites and in advertisements are fairly straightforward. HHS has stated that the disclosure of physician ownership may be made in a single location within a hospital's public website, such as the home page or an "About Us" section, so long as it includes a list of physician owners "in a conspicuous place" and that physician ownership information be "readily legible and in a size that is consistent with other text on the Website."²⁶ In the case of advertising disclosure, HHS expressed the view that a sentence to the effect that the

hospital is partially owned or invested in by physicians should satisfy the requirements. This language should be clear and readable in print communications and should be included in any radio or media advertisements as well.

Conclusion

The changes to the whole hospital exception have created a number of difficult challenges for physician-owned hospitals and may in fact occasion the sale or demise of many of these facilities.²⁷ For those institutions that are determined to survive, the law requires compliance with standards that are not well defined in an environment where the consequences for non-compliance are extremely serious. Further clarification of the rules surrounding the exception is essential to promote compliance with the law and avoid significant disruptions in the delivery of services by these facilities.

1 42 U.S.C. § 1395nn.

2 42 U.S.C. § 1395nn(a)(1)(B).

3 Pub. L. No. 103-66, 107 Stat. 596 (1993).

4 Some of the concerns expressed by federal agencies and competing providers are discussed in L. Bauman (Ed.), *HEALTHCARE FRAUD AND ABUSE: PRACTICAL PERSPECTIVES* 151 (2d Ed. 2008).

5 75 Fed. Reg. 71800 (Nov. 24, 2010).

6 75 Fed. Reg. 72250.

7 Codified as Social Security Act (SSA) § 1877(i)(1)(D). All subsequent statutory references will be cited to the SSA, rather than 42 U.S.C. § 1395nn, as the former is the reference used in PPACA and the Regulations.

8 *Id.* (emphasis supplied).

9 75 Fed. Reg. 72250 (emphasis supplied).

10 75 Fed. Reg. 72242 (emphasis supplied).

11 *E.g.*, SEC Rule 13d-1, 17 C.F.R. § 240.13d-1.

12 42 C.F.R. § 411.354(b)(1).

13 42 C.F.R. § 411.362(b)(4).

14 75 Fed. Reg. 72246. No guidance had been issued as of this article's submission.

15 42 C.F.R. § 411.353(b)(5).

16 42 C.F.R. § 411.354(b)(5)(ii).

17 SSA § 1877(i)(1)(B).

18 75 Fed. Reg. 72243, 42 C.F.R. § 411.362(b)(2).

19 75 Fed. Reg. 72244, 72245.

20 SSA § 1877(i)(3)(G).

21 75 Fed. Reg. 72243.

22 SSA § 1877(i)(3)(E).

23 42 C.F.R. § 411.362(b)(3)(ii)(A). There are also specific requirements as to the timing of the notice to be given by physicians and the obligations in exigent circumstances, e.g., emergency room admissions, that are not directly binding on a hospital.

24 42 C.F.R. § 489.20(u).

25 75 Fed. Reg. 72247-8.

26 75 Fed. Reg. 72248.

27 While not directly related to the enactment of PPACA § 6001, it is significant that MedCath, a leading operator of physician-owned specialty hospitals, determined to sell substantially all of its assets as of September 2011. See <http://phx.corporate-ir.net/phoenix.zhtml?c=129804&p=irol-newsArticle&iD=1609395&highlight>.

PPACA Section 3025: The Hospital Readmissions Reduction Program

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Introduction

It is impossible not to notice a focus by government agencies on healthcare quality initiatives and promoting efficiency of care, and the Patient Protection and Affordable Care Act of 2010¹ (PPACA) is no exception, loaded up with various rules and programs with those efforts in mind. One such program promulgated under PPACA is the hospital readmissions reduction program, which stems from a general perception of higher hospital readmission rates being associated with higher costs and lower quality during and after the initial hospital stay.² The underlying premise is that readmission rates can be reduced by taking such actions as improving information exchange between hospital discharge planners and post-acute providers, improving patient communications, and reducing medical errors.³

PPACA Section 3025 establishes the hospital readmissions reduction program, designed to ensure appropriate care to individuals discharged and to avoid hospital readmission, which by one estimate can cost the government upwards of \$15 billion, with \$12 billion identified as potentially preventable.⁴ This program will subject hospitals with a high rate of potentially preventable Medicare readmissions to Medicare payment reductions. The structure of the program includes a complicated calculation that will result in adjustments to hospital payments based on the dollar value of each hospital's percentage of potentially preventable Medicare readmissions. Initially, the program will focus on readmissions for acute myocardial infarction (AMI) (heart attacks), heart failure (HF), and pneumonia (PN), which are the three conditions with risk-adjusted readmission measures that have been endorsed by the National Quality Forum (NQF) and adopted as the initial "applicable conditions" under the program.⁵

The hospital readmissions reduction program is not without criticism and controversy. Since the program's introduction, stakeholders have been analyzing the potential effect on a hospital's discharge process, as well as the impact on long term care and other post-discharge providers. Although many questions remain open regarding the penalty calculation, and many stakeholders continue to scrutinize various aspects of the program, including the basic tenet of whether focusing on readmission rates actually yields better quality of care, the program's start date is set for

October 1, 2012, and all concerned providers need to be in full preparation mode at this time. This article provides an overview of the program, the available regulations and guidance, and what is to come over the next few months.

Where Are We Now—PPACA Section 3025 and the Proposed and Final FY 2012 IPPS Rules

PPACA Section 3025 (as amended by Section 10309 of PPACA) amended Section 1886 of the Social Security Act (SSA) (42 U.S.C. Section 1395ww) ("Payment to Hospitals for Inpatient Hospital Services") by adding a new subsection (q). This subsection (q) is the statutory text that establishes the hospital readmissions reduction program effective for discharges from applicable hospitals. It sets forth the general rules regarding the calculation for payment adjustments due to certain excessive readmissions and is scheduled to become effective as of October 1, 2012.⁶

In the 2012 Inpatient Prospective Payment System (IPPS) rule-making, the Centers for Medicare & Medicaid Services (CMS) first introduced the initial framework and certain proposals for the hospital readmissions reduction program.⁷ CMS limited the discussion to the following features of the program:

1. Aspects that relate to the applicable conditions and readmissions to which the program applies in the first year beginning October 1, 2012;
2. Readmission measures and related methodology used for those measures and the calculation of the readmission rates; and
3. Public reporting of readmission data.⁸

Both the proposed and final rules also indicated that CMS would defer addressing details regarding payment adjustment to fiscal year (FY) 2013, stating that:

Specific information regarding the payment adjustment required under section 1886(q) of the Act will be proposed in next year's IPPS/LTCH PPS proposed rule. Although we did not propose specific policies regarding the payment adjustment under the Hospital Readmissions Reduction Program in the FY 2012 IPPS/LTCH PPS proposed rule, we believe that it is still important to set forth the general framework of the Hospital Readmissions Reduction Program, including the payment adjustment provisions, in order for the public to understand how the measures discussed and finalized in this rulemaking will affect certain hospital payments beginning in FY 2013.⁹

Moreover, CMS intends to continue to add program requirements beyond FY 2013 through future IPPS rulemaking cycles, making this a phased implementation process. So some uncertainty will remain as to the ultimate scope and requirements of this program.

General Calculation/Formula for Adjustment

To account for excess “readmissions,” payment for discharges from an “applicable hospital” (this includes a hospital reimbursed under IPPS and a hospital paid under a state waiver from IPPS)¹⁰ will be equal to the “base operating DRG [diagnosis-related group] payment amount” for the discharge multiplied by the “adjustment factor” for the FY.¹¹ Put simply, the base operating DRG payment amount will be reduced by an adjustment factor that accounts for excessive readmissions.

The term “readmission” is defined as an admission that follows a discharge related to an applicable condition at the same or different hospital within a time period set forth by the Secretary of the U.S. Department of Health and Human Services (Secretary). The statute specifically provides that a readmission is:

in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.¹²

The program is structured such that payment adjustments will be determined based on the occurrence of readmissions for “applicable conditions.” Applicable conditions selected under this program are to be conditions associated with readmissions of high volume/high expenditure and having “endorsed”¹³ readmission measures that have exclusions for readmissions unrelated to the prior discharge (such as planned readmission or transfer to another applicable hospital). However, CMS indicated in the FY 2012 IPPS Proposed Rule that these proposed measures otherwise “include readmissions for all causes, without regard to the principal diagnosis of the readmission.”¹⁴

As indicated above, the initial applicable conditions under this program will be AMI, HF, and PN. CMS considers each of these conditions to satisfy these criteria, and each was identified by the Medicare Payment Advisory Committee (MedPAC) in its 2007 Report to Congress as being among the seven conditions and procedures associated with roughly 30% of readmissions that are potentially preventable.¹⁵ Further, because the NQF-endorsed measures reflect calculations over a thirty-day period, CMS proposed thirty days from discharge as the time period for counting subsequent admissions as readmissions.¹⁶ After considering public comment, CMS finalized the proposed definition of readmission and the thirty-day time period.¹⁷ Beginning in FY 2015, the four additional conditions MedPAC identified in its 2007 report will be added, as well as any other conditions and procedures that the Secretary determines to be appropriate.¹⁸

The “base operating DRG payment amount” is the payment amount that otherwise would be made under SSA Section 1886(d) for a discharge, decreased by any portion of such



payment amount that is attributable to outlier, indirect medical education, disproportionate share, and low-volume hospital payments.¹⁹ In addition, there are special rules for defining the payment amount that otherwise would be made under SSA Section 1886(d) that offer some leniency for Medicare-dependent small rural hospitals, sole community hospitals, and hospitals paid under SSA Section 1814(b)(3). Note that in the FY 2012 IPPS Proposed Rule, CMS stated that it intends “to propose regulations to implement the statutory provisions related to the definition of ‘base operating DRG payment amount’ in the FY 2013 IPPS/LTCH PPS proposed rule.”²⁰

The “adjustment factor” in the equation to account for excess readmissions is CMS’ financial stick that will reduce discharge dollars under the hospital readmissions reduction program. This is where the calculation becomes more complicated, having many ratios and layers that must be captured into the overall number. The adjustment factor for an applicable hospital for a fiscal year is equal to the *greater of* a specified “ratio” for the hospital (see below) for the “applicable period”²¹ for such FY or the floor adjustments as follows:

- FY 2013—floor is 0.99;
- FY 2014—floor is 0.98; and
- FY 2015 and subsequent FYs—floor is 0.97.²²

Thus, payment reductions for Medicare billings will be capped at 1% for FY 2013, 2% for FY 2014, and 3% for FY 2015 and beyond.

As to the specified “ratio,” it is defined as being equal to one minus the ratio of the “aggregate payments for excess readmissions” and the “aggregate payments for all discharges,” both of which are further defined in the statute and offer an additional

layer of complication.²³ As discussed above, if the specified ratio is greater than the applicable floor adjustment, then the adjustment factor will be such specified ratio.

The calculation for the “aggregate payments for excess readmissions” includes an “excess readmission ratio” (another layer to the overall equation), and the statute requires the number of readmissions used in that ratio to be risk adjusted.²⁴ What that means is the ratio must be adjusted for differences in how sick patients were before being admitted to the hospital. CMS describes this as:

comparing hospitals’ readmission rates, to account for differences in the severity of illness of the patients that hospitals treat. Risk adjustment essentially “levels the playing field” for comparing hospital performance by taking into account that some hospitals’ patients are sicker than others on admission and therefore have a higher risk of readmission.²⁵

Such risk adjustments will be based on age and sex demographic factors and various comorbidities.²⁶ Note, however, that certain commenters have argued that such additional demographic factors as race, language, life circumstances, and socioeconomic factors also should be included to avoid punishing hospitals that primarily serve socioeconomically challenged communities.²⁷

Further, for each of AMI, HF, and PN, the excess readmission ratio will be a “risk standardized” ratio, which can be conceptualized as having risk-adjusted *actual* readmissions as its numerator and risk-adjusted *expected* readmissions as its denominator. The numerator is intended to reflect the probability of readmission at a particular applicable hospital. The denominator is intended to reflect the “averaged” probability of readmissions across hospitals considering a similar case mix. CMS explains this:

ratio compares the total adjusted actual readmissions at the hospital to the number that would be expected if the hospital’s patients were treated at an average hospital with similar patients. Hospitals with more adjusted actual readmissions than expected readmissions will have a risk-standardized ratio (excess readmission ratio) greater than one.²⁸

But what if a hospital disagrees with CMS’ findings? Basically, its options will be limited. While hospitals will have the opportunity to review and submit corrections to information made public, there will be no administrative or judicial review available for: (1) the determination of base operating DRG payment amounts; (2) the methodology for determining the adjustment factor (including excess readmissions ratio, aggregate payments for excess readmissions, aggregate payments for all discharges, applicable periods, and applicable conditions), and (3) the measures of readmissions.²⁹

What Hospitals Should Be Thinking About

The hospital readmissions reduction program is being implemented over several rulemaking cycles. Up to now, CMS gener-

ally has indicated how it will calculate various key variables (as discussed above). But CMS has yet to say how payment adjustments will actually be made based on such calculations when this program goes live, though it has stated it will take this issue up this year in 2012 for application in FY 2013. Until then, hospitals face uncertainty as to how they may be affected financially and precisely what they should be doing now to minimize such effect.

Nonetheless, it is clear that hospitals will have a financial incentive to reduce readmissions following discharges related to applicable conditions. How can this be done? MedPAC, in its 2007 Report to Congress, offered a number of suggestions. Generally speaking, these include providing safer inpatient care to decrease the chance of readmissions (e.g., reducing infection), avoiding post-discharge complications by adopting appropriate post-discharge medication protocols, improving communications with patients before and after discharge, and improving communications with post-acute care providers. Focusing on HF, CMS has stated that “improved hospital and post-discharge care, including pre-discharge planning, home-based follow-up, and patient education have been shown to lower heart failure readmission rates, suggesting that heart failure readmission rates might be reduced if proven interventions were more widely adopted.”³⁰

This clearly envisions a vital role for hospital discharge-planning and case-management staff. There also has been recent movement for hospitals to affiliate with post-acute providers, such as home health agencies and nursing facilities, to coordinate care and thus reduce potentially preventable readmissions. In structuring and aligning incentives under such arrangements, care must be taken to ensure compliance with federal laws such as the Anti-Kickback Statute and Stark Law, as well as any analogous state laws.

Conclusion

For hospitals already operating under tight budgetary constraints, the hospital readmissions reduction program has the potential for posing additional difficulties. How much so will depend in part on a hospital’s ability to coordinate with post-acute providers, patients, and patient caregivers in improving post-discharge care—as well as on its ability to control inpatient infection rates and occurrence of medical errors. This will also depend on how CMS will implement various aspects of this program going forward, including financial penalties, of which we should learn more this year. In addition, whether this program actually represents a level playing field for all applicable hospitals serving various and diverse communities will depend heavily on how effective the risk-adjustment factors that have been selected (which include, in addition to comorbidities, only two demographic variables—age and sex) are in achieving truly risk-standardized comparisons.

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(404) 873-8594 or at neil.hoffman@agg.com. This article presents information on legal matters of general interest in summary form and should not be construed as legal advice or opinion on specific matters.

- 1 Pub. L. No. 111-148.
- 2 73 Fed. Reg. 48434 (Aug. 19, 2008) (Inpatient Prospective Payment System Update for Fiscal Year 2009).
- 3 See, e.g., Congressional Research Service Report for Congress: Medicare Hospital Readmissions: Issues, Policy Options and PPACA (2010).
- 4 Medicare Payment Advisory Commission (MedPAC), Report to Congress: Promoting Greater Efficiency in Medicare (2007).
- 5 76 Fed. Reg. 25788, 25929 and 25932 (May 5, 2011); CCH's Law, Explanation and Analysis of the Patient Protection and Affordable Care Act, Including Reconciliation Act Impact, Vol. 1, ¶ 749, pp. 401-403 (2010); Social Security Act (SSA) § 1886(q)(5)(A) (defining "applicable condition").
- 6 SSA § 1886(q)(1).
- 7 On May 5, 2011, CMS released the federal fiscal year (FFY) 2012 proposed payment rule for the Medicare IPPS (FY 2012 IPPS Proposed Rule) (76 Fed. Reg. 25788 (May 5, 2011)), which was followed by the (FFY) 2012 final payment rule for the Medicare IPPS (FY 2012 IPPS Final Rule) released on August 18, 2011 (76 Fed. Reg. 51476 (Aug. 18, 2011)).
- 8 76 Fed. Reg. at 51661 (Aug. 18, 2011); 76 Fed. Reg. at 25929 (May 5, 2011).
- 9 76 Fed. Reg. at 51661 (Aug. 18, 2011); 76 Fed. Reg. at 25929-25930 (May 5, 2011).
- 10 SSA § 1886(q)(5)(C) specifically defines an "applicable hospital" subject to the readmissions reduction program as an SSA § 1886(d) hospital or a hospital that is paid under SSA § 1814(b)(3).
- 11 SSA § 1886(q)(1); 76 Fed. Reg. at 25930 (May 5, 2011).
- 12 SSA § 1886(q)(5)(E).
- 13 The measures are endorsed by NQF, which is the entity under contract with the government for performance measurement pursuant to SSA § 1890(a).
- 14 76 Fed. Reg. at 25933 (May 5, 2011).
- 15 76 Fed. Reg. at 51665 (Aug. 18, 2011). The remaining four conditions are chronic obstructive pulmonary disease, coronary artery bypass graft surgery, percutaneous transluminal coronary angioplasty, and other vascular procedures.
- 16 76 Fed. Reg. at 25932 (May 5, 2011).
- 17 76 Fed. Reg. at 51666 and 51670 (Aug. 18, 2011).
- 18 SSA § 1886(q)(5)(B).
- 19 SSA § 1886(q)(2)(A); 76 Fed. Reg. at 25930 (May 5, 2011).
- 20 76 Fed. Reg. at 25930 (May 5, 2011).
- 21 SSA § 1886(q)(5)(D) authorizes the Secretary to specify the applicable period with regard to a FY. For FY 2013, CMS has decided to utilize "3 years of data (three 12-month increments) to calculate the three proposed readmission measures." 76 Fed. Reg. at 51671 (Aug. 18, 2011).
- 22 SSA § 1886(q)(3)(C).
- 23 SSA §§ 1886(q)(4) and (q)(3)(B).
- 24 SSA § 1886(q)(4)(C).
- 25 76 Fed. Reg. at 25934 (May 5, 2011).
- 26 76 Fed. Reg. at 51670 (Aug. 18, 2011); 2010 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-Day Risk-Standardized Readmission Measures.
- 27 76 Fed. Reg. at 51670-51671 (Aug. 18, 2011). HFMA Comments on Proposed Readmissions Reduction Program in FFY12 IPPS Proposed Rule. Healthcare Financial Management Association (June 20, 2011), available at www.hfma.org/Templates/InteriorMaster.aspx?id=27497.
- 28 76 Fed. Reg. at 25937 (May 5, 2011).
- 29 SSA §§ 1886(q)(6)(B) & (7).
- 30 76 Fed. Reg. at 25929 (May 5, 2011) (citations omitted).

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The Required Hospital Standard Charge Publication That You Probably Missed

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A little-known provision of the “medical loss ratio” standards contained in the Patient Protection and Affordable Care Act of 2010 (PPACA) requires all hospitals to “establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital’s standard charges for items and services provided by the hospital, including for diagnosis-related groups . . .” (Publication Requirement).¹

Although this statutory mandate is technically in effect, a cursory review of hospital and health system websites indicates that few seem to currently comply with the same.² To date, the U.S. Department of Health and Human Services (HHS) has not provided guidelines regarding the implementation of the Publication Requirement. Even though HHS has been silent on the issue, previous federal legislation and state efforts provide insight into what the regulations may look like when issued.

Federal Pricing Transparency Initiatives in the Years Leading Up to PPACA

The push toward transparency in healthcare costs is not a foreign concept to healthcare industry stakeholders. PPACA sets forth a number of transparency provisions, including requiring disclosures by device manufacturers of payments or transfers of value to physicians or teaching hospitals, disclosures by group purchasing organizations of certain physician ownership or investment interests, and disclosures by drug manufacturers and distributors regarding the drug samples they distribute to practitioners.

Executive Order 13410

Even prior to PPACA, the previous administration made transparency in healthcare a priority. In 2006, President George W. Bush issued Executive Order 13410 with the stated purpose of promoting the efficient delivery of quality care by promoting increased transparency with respect to healthcare pricing.³ The Executive Order required federal agencies to make available to enrollees of federal healthcare programs the prices that the federal agency, its health insurance issuers, or its health insurance plans pay for procedures to enrolled healthcare providers. The Executive Order also required that such entities, in collaboration with multi-stakeholder groups, develop “information regarding the overall costs of services for common episodes of care and treatment of common chronic diseases.”⁴ Of course, this Executive Order only

pertained to federal agencies, but it was nonetheless an early example of the federal government seeking more transparency in healthcare costs.

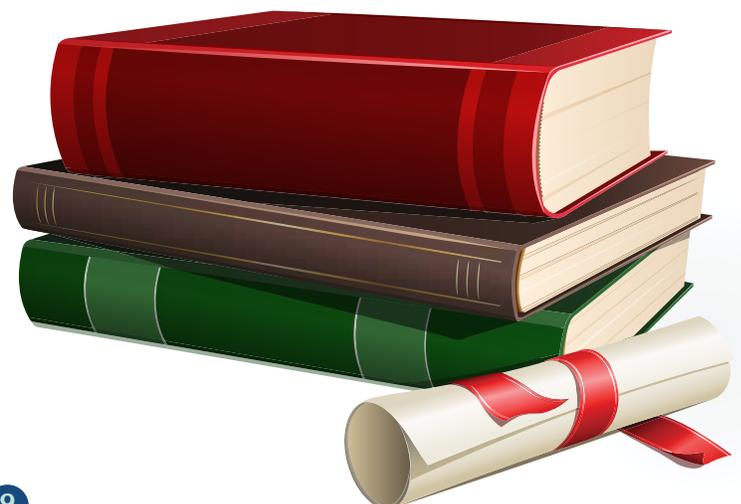
The Health Care Price Transparency Promotion Act of 2009 (HR 2249)⁵

HR 2249 was introduced in May 2009, but was never enacted by Congress. HR 2249 would have, if adopted, required states to establish laws mandating that certain pricing disclosures be made by hospitals in those states. Specifically, under HR 2249, states would have to adopt laws requiring hospitals to disclose pricing information on inpatient and outpatient hospital services (with each state determining the specific services for which they would require disclosure). HR 2249 would have required the states to mandate that hospitals provide access to this information, in some undefined manner, to those seeking or requiring the services. Moreover, the bill sought to require states to obligate hospitals, upon request by a consumer, to provide a statement of the estimated out-of-pocket costs that were likely to be incurred by an individual if the individual receives particular healthcare items and services within a specified period of time.

The Transparency in All Health Care Pricing Act of 2010 (HR 4700)⁶

HR 4700 was introduced in the House in February 2010, but also was not passed into law. HR 4700 sought to require that “any and all individuals or business entities, including hospitals, physicians, nurses, pharmacies, pharmaceutical manufacturers, dentists, and the insurance entities . . . and any other health care related providers or issuers that offer or furnish health care related items, products, services, or procedures (as defined by the Secretary of Health and Human Services) for sale to the public shall publicly disclose, on a continuous basis, all prices for such items, products, services, or procedures in accordance with this section.”⁷

HR 4700, if adopted, would have required healthcare providers and suppliers to make disclosures: (1) in an open and conspicuous manner; (2) available in print, at the point of purchase, and on the Internet; and (3) include all wholesale, retail, subsidized, discounted, or other such prices the healthcare providers accept as payment in full for the items, products, services, or procedures that



are furnished to patients. The penalties for failure to disclose such information would have resulted in civil fines or other civil penalties as deemed appropriate by the HHS Secretary.

State Initiatives Regarding Healthcare Pricing Transparency

In addition to federal initiatives, many states have adopted laws regarding transparency and disclosure of hospital charges.⁸ Most of the state initiatives share the common stated goal of increasing pricing transparency for the states' healthcare consumers. Though the states' approaches to achieving that common goal vary, California's approach is illustrative of the types of issues addressed when states attempt to increase healthcare pricing transparency.

California's Payers' Bill of Rights

Beginning July 1, 2004, as part of its Payers' Bill of Rights,⁹ California hospitals (with the exception of small and rural hospitals) are required to make two types of disclosures regarding their rates and charges: (1) disclosures to the public; and (2) disclosures to the state licensing office. The state licensing office, in turn, must aggregate and make much of this information publicly available on its website. A hospital's failure to comply with the provision can result in civil penalties of \$100 per day that the hospital delays reporting.

California hospitals are required to disclose information to the public by either: (1) making available certain service charge-related information; or (2) making specific information available to the uninsured. A California hospital must post on its website, or provide via an electronic or written copy at the hospital, a copy of its "charge description master."¹⁰ "Charge description master" is defined by the statute to mean "a uniform schedule of charges represented by the hospital as its gross billed charge for a given service or item, regardless of payer type."¹¹ If the hospital has an emergency department, it is required to post a "clear and conspicuous notice" in its admissions office and billing office informing patients that the hospital's charge master is available.¹² Hospitals must also file a copy of their charge description master with the state licensing office.¹³ Moreover, hospitals must annually calculate an estimate of the percentage increase in the hospital's gross revenue as a result of any price increase for charges for patient services during the preceding year.¹⁴

In addition to the charge description master information, hospitals must compile a list of their twenty-five most common outpatient procedures and the average charges for such procedures, and then submit them annually to the state's licensing office.¹⁵ The licensing office is then required to compile a list of the twenty-five most commonly performed inpatient procedures in California hospitals, and publish the average charges for those procedures for each hospital. Upon request by a patient, a California hospital must provide a copy of such information.¹⁶ California publishes this information on its Office of Statewide Health Planning and Development

website wherein users may find the prices for all goods and services furnished at California hospitals.¹⁷

With respect to the uninsured, upon request, the hospital must provide a written estimate of the amount the hospital will require the person to pay for the healthcare services, procedures, and supplies that are reasonably expected to be provided to the person by the hospital, based upon an average length of stay and services provided for the person's diagnosis.¹⁸ In addition to the cost information, the hospital must also provide the uninsured patient with information about its financial assistance and charity care policies, and contact information for a person who has more information.¹⁹

Practical experience with California hospitals indicates that compliance with the various mandates can be costly.

Predictions Regarding the Publication Requirement

While HHS has not yet issued proposed regulations on the Publication Requirement, based on past federal legislative initiatives and the experiences of the states, a number of predictions can be made regarding their contents.

Standard Charges

How HHS defines the "standard charges" that must be published will likely be controversial.

In U.S. Securities and Exchange Commission filings, a number of publicly traded hospitals and health systems have already begun disclosing as a risk factor that complying with PPACA's "standard charge" publication/disclosure requirement could adversely affect their competitiveness and patient volumes.²⁰ A comparative analysis of the hospital's standard charges (as in California) or the calculation and disclosure of wholesale, retail, subsidized, and/or discounted prices as well as the amount the hospital accepts as payment in full for services (as in HR 4700), is likely to be a time-consuming, costly, and complex undertaking. Further, such a standard has the potential to cause consumer confusion since the lower prices charged to payors reflects complex payment/risk variables.

Shedding light on what may be in store for "standard charges," various sources have reported that HHS has created a task force charged with developing the regulations implementing the Publication Requirements (Task Force).²¹ According to these reports, the Task Force has preliminarily determined that requiring complete pricing and payment disclosure may be unrealistic, but nevertheless is considering mandating disclosures that are substantially similar to those that would have been required by HR 4700, including:

1. The amount billed for services;
2. The median in-network insurance contracted amount that the hospital accepts as payment-in-full for the services rendered;
3. The median out-of-network amount charged for services; and

4. The amount Medicare reimburses the hospital for the services rendered.

Of course, these proposals are a work in progress, and nothing has been officially made public yet. Further, it is important to note that the four reported proposals do not include a consideration of other pertinent areas that affect a hospital's pricing, such as Medicaid's comparatively low reimbursement, patient volume, and payor mix. Given the expansion of Medicaid contemplated under PPACA, such information will be increasingly relevant and will likely have a greater impact on the average cost of healthcare.

Posting

The Publication Requirement will almost certainly require that the standard charges be posted on the hospital's website (as under HR 4700 and California law). In order to further inform patients of their right to see the hospital's standard charges, it is also likely that the Publication Requirement will require clear and conspicuous *physical posting* of notices in hospital facilities (similar to HR 4700 and California law). Additionally, as with California's law, it is reasonable to assume that HHS will also require hospitals to furnish their standard charge information in a non-Internet-based form upon patient request.

Penalties

Even though the statute does not discuss penalties for failure to comply with the Publication Requirement, most state laws include a punitive aspect. Similar to HR 4700 and California's statutes, it is likely that HHS will establish that failure to comply with the Publication Requirements will result in the imposition of civil monetary penalties.

State Law Preemption

It remains to be seen if the federal Publication Requirement will preempt or conflict with state laws currently in effect. For multi-state hospital systems that currently have to comply with many duplicative and varying state disclosure/publication laws, a preemptive federal Publication Requirement may be seen as a welcomed uniform standard.

Conclusion and Recommended Actions

Though the effective date of the Publication Requirement was initially debatable due to unclear statutory language, it is clear that the federal Publication Requirement now is currently in effect, though not necessarily widely complied with as of yet.

Though the HHS Secretary has not issued regulations regarding the Publication Requirement, hospitals can likely expect, and begin preparing for, some of the following provisions:

- Additional administrative processes to determine and calculate the hospital's "standard charges";
- Required publication of the standard charges on the hospital's website;

- Physical posting requirements for hospital facilities;
- Required procedures for a consumer to obtain the information in a manner other than visiting the hospital's website; and
- Imposition of civil monetary penalties for failure to comply.

Even with the lack of direction from HHS at this time, making it unclear what the precise compliance requirements are, hospitals can begin to assemble response teams tasked with implementing the Publication Requirement.

Further, hospitals should begin to take steps toward increasing transparency since, regardless of the ultimate U.S. Supreme Court disposition of PPACA, the push for increased transparency will continue. Though the move toward increased transparency will pose additional challenges, hospitals should consider using their proactive transparency efforts as a positive marketing opportunity.²²

Hospitals can further develop and advertise services for providing non-binding price quotations/estimates, and otherwise come up with innovative ways to ease and embrace the march toward transparency.

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- 1 Patient Protection and Affordable Care Act § 2718; 42 USCA § 300gg-18(e) (2010).
- 2 Initially, there were disagreements as to when the Publication Requirement was to become effective (March 3, 2010, or January 1, 2011). There are still possible arguments as to why an individual hospital or health system is not yet in compliance with the provision, including the fact that HHS has not yet issued regulations and there are no stated penalties for noncompliance. Moreover, the paucity of hospitals actually complying (or attempting to comply) with the Publication Requirement indicates that failing to currently comply is low-risk. However, despite these positions, the Publication Requirement, whatever it may be, is currently in effect.
- 3 Exec. Order No. 13410, 71 Fed. Reg. 51089 (Aug. 28, 2006), available at www.gpo.gov/fdsys/pkg/FR-2006-08-28/html/06-7220.htm.
- 4 *Id.* at 51090.
- 5 The Health Care Price Transparency Promotion Act of 2009, HR 2249, 111th Cong. (2009), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d111:HR.2249>.
- 6 The Transparency in All Health Care Pricing Act of 2010, HR 4700, 111th Cong. (2010), available at <http://thomas.loc.gov/cgi-bin/query/z?c111:HR.4700>.
- 7 *Id.* (emphasis added).
- 8 See, e.g., Madeline Kreischer et al., State Legislation Relating to Transparency and Disclosure of Health and Hospital Charges, National Conference of State

Legislatures, October 2011, www.ncsl.org/issues-research/health/transparency-and-disclosure-health-costs.aspx.

9 Cal. Health & Safety § 1339.50 *et seq.*

10 Cal. Health & Safety § 1339.51.

11 *Id.*

12 *Id.*

13 *Id.* at § 1339.55.

14 *Id.*

15 *Id.* at § 1339.56.

16 *Id.*

17 See www.oshpd.ca.gov/HID/DataFlow/index.html. A link to the Guide may be found here: www.dshs.state.tx.us/thcic/consumerguide/consumerguide.shtm.

18 *Id.* at § 1339.585.

19 *Id.*

20 See, e.g., www.knowledgemosaic.com/Gateway/SECData/PDF-Cache/11/0000950123-11-036130/kmcomposite.pdf. See also www.springsgov.com/units/Communications/MHS/HCA/Exhibits/Exhibit%20E/2.pdf.

21 See, e.g., Healthcare Aware—Keeping You Informed on PPACA, Aug. 8, 2011, www.unifiedgrp.com/2011/08/08/enews_090111_healthcare_aware/.

22 For a good example of a positive marketing campaign using the Publication Requirement, see Hospital Corporation of America's "Pricing and Financial Information" webpage, available at <http://hcahealthcare.com/pricing-financing/>.

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Religion and Health Insurance Exchanges

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The debate about religion and the Patient Protection and Affordable Care Act of 2010 (PPACA) (PL 111-148) is far from hidden. Issues regarding reproductive issues regularly hit the news. In addition, in the news is the potential unconstitutionality of health insurance exchanges required under the PPACA. Public opinion and the upcoming election, as well as the U.S. Supreme Court will decide the fate of these provisions. What might come as a surprise is the additional provider conscience protections added in PPACA related to these hotly contested health insurance exchanges. These provisions are already in effect for healthcare providers without need for any future rulemaking. Below is a summary of the current provider conscience protections and enforcement as well as the new PPACA provision.

Federal Healthcare Conscience Protection Statutes

The provider conscience protections have been well established since the 1970s with a series of laws called the Federal Health Care Conscience Protection Statutes. These statutes include:

- [Church Amendments](#) (42 USC Section 300a-7);
- [Public Health Service Act](#) (42 USC Section 238n); and
- [Weldon Amendment](#) (Consolidated Appropriations Act, 2009, PL 111-117).

Under the Federal Health Care Conscience Protection Statutes, recipients of certain federal funds are prohibited from discriminating against healthcare providers based on the objection to, participation in, or refusal to participate in specific medical procedures and related training and research activities. Such medical procedures include abortions and sterilizations. Healthcare providers may not be coerced into performing procedures that a healthcare worker finds religiously or morally objectionable. Under these statutes, healthcare providers include physicians but may also include facilities such as hospitals.

OCR Enforcement

The agency tasked with enforcing provider conscience protections is the Office for Civil Rights (OCR) of the U.S. Department of Health and Human Services (HHS), the office also tasked with enforcement of the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and other civil rights laws. OCR is responsible for receiving and investigating complaints of discrimination based on the Federal Health Care Conscience Protection Statutes. Those filing a complaint based on the Federal Health Care Provider

Conscience Protection laws are asked to complete a [Civil Rights Discrimination Complaint Form Package](#). OCR instructs on its website that a provider check the “other” box related to the type of discrimination and write “Conscience Protection.”

On February 18, 2011, HHS and OCR announced the [Conscience Protection Rule](#). The Conscience Protection Rule, effective March 25, 2011, rescinded in part and revised a December 19, 2008, rule entitled “*Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law*” in the hopes to clarify confusion under this old regulation. These changes came after eight states filed suit in *Connecticut v. United States* in the U.S. District Court for the District of Connecticut. The states argued that HHS exceeded its statutory authority in violation of the Administrative Procedure Act by failing to provide adequate public comments and that the regulations were vague and overbroad.

The current rule sets out the rule’s purpose, which is to enforce the Federal Health Care Conscience Protection Statutes and designates OCR to receive those complaints for HHS (45 CFR Section 88.1, 88.2). All other provisions of the prior rule were rescinded. Although the Conscience Protection Rule from HHS rescinded provisions of the prior rule, it does not modify the provider conscience provisions of Federal Health Care Conscience Protection Statutes and PPACA, because regulations are not needed to make such laws effective.

Health Insurance Exchanges

PPACA included healthcare conscience protections within the health insurance exchange system provisions providing additional protections to the already well-established Federal Health Care Conscience Protection Statutes. More specifically, Section 1303(b)(4) of PPACA provided that, “No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provider coverage of, or refer for abortions.” This section is currently in effect regardless of recent HHS rulemaking. This provision is the first provider conscience statutory provision passed recently, although pending legislation does exist backed by religious leaders concerned over sterilization and contraceptive coverage in PPACA.

It All Could Change

As with many provisions of PPACA, these provider conscience protections for hospitals and physicians related to health insurance exchanges may not exist next year. These changes may come from a repeal of the individual insurance mandates and health insurance exchanges or from a decision from the U.S. Supreme Court. For those who represent religious hospitals and physicians, Section 1303(b)(4) reminds us of the protections already in place for our clients. For the rest of us, it is a good reminder of the enforcement authority of OCR and our obligation to advise our clients on these issues raised in a well-established area of civil rights.

Reporting and Returning Overpayments: Complications, Risks, and Headaches Under PPACA

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Introduction

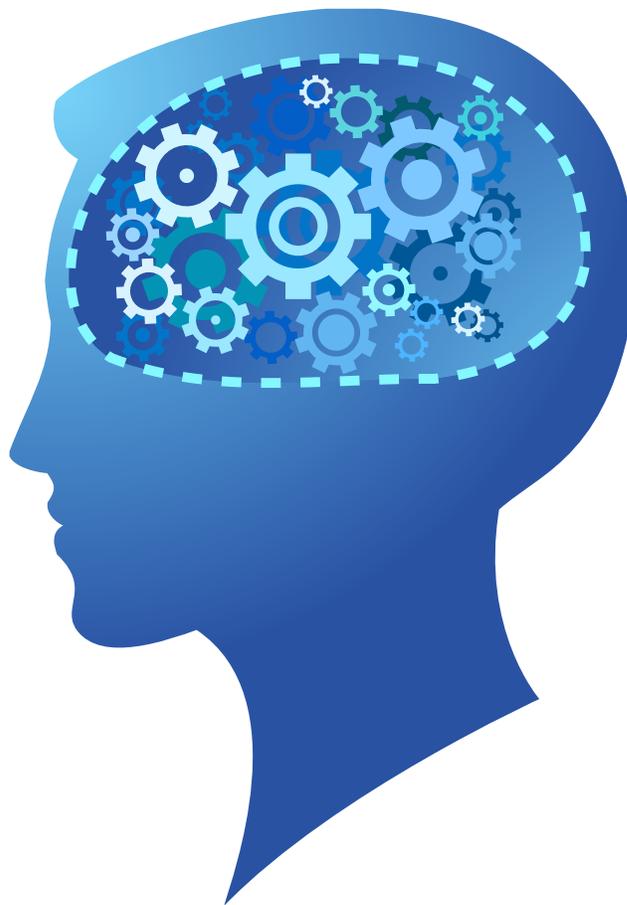
In Fiscal Year 2011, the U.S. Department of Justice recovered more than \$3 billion as a result of False Claims Act (FCA) settlements and judgments. Healthcare recoveries accounted for 83% (\$2.5 billion) of that total.¹ On September 7, 2011, DOJ arrested ninety-one people in eight states and charged them with attempting to steal \$295 million from Medicare in what was the largest Medicare arrest to date.² These anti-fraud measures—so unprecedented in scale—were the result of a concerted governmental effort to curb fraud within the healthcare industry.

The latest weapon in the government's arsenal is a provision in the Patient Protection and Affordable Care Act of 2010 (PPACA) that takes aim at overpayments and significantly increases the organizational risk involved with retaining an overpayment for healthcare services. Section 6402(d) (Reporting and Returning of Overpayments) of PPACA requires a provider to report and return an overpayment to the appropriate Medicaid state agency or Medicare contractor within sixty days of its identification. The provider must also supply, in writing, an explanation for the overpayment. This provision applies to healthcare providers, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, and Prescription Drug Plan sponsors. The retention of an overpayment beyond sixty days, no matter how innocuous, is a violation of the FCA. Thus, the FCA will play an important role in determining the ramifications of retaining an overpayment.

FCA, FERA, and PPACA: The Triumvirate of Healthcare False Claims Liability

FCA

The FCA is the government's primary enforcement mechanism against fraud. The act imposes civil liability on any person who knowingly uses a "false record or statement to get a false or fraudulent claim paid or approved by the Government," or any person who "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid."³ In addition to policing fraud, the FCA is also a significant source of revenue, thanks to its provision for treble damages and penalties ranging from \$5,500 - \$11,000 per violation. In fact, the Obama Administration touted



FCA recoveries as a source that would be central to financing healthcare reform.⁴

To incentivize FCA actions, the law empowers private parties to bring a qui tam action on behalf of the United States. Historically, the qui tam suit was an English common law device that permitted citizens to prosecute a claim on the King's behalf. Like its English predecessor, the modern qui tam plaintiff—a "relator"—shares in the recovery from a successful claim, with the percentage varying based on whether or not the government chooses to intervene in the action.

The Fraud Enforcement and Recovery Act

The FCA has undergone more than one makeover since its enactment back in 1863, including in May 2009 when President Barack Obama signed the Fraud Enforcement and Recovery Act⁵ (FERA) into law. The FERA amended the FCA's provision dealing with reverse false claims, which occur when a party attempts to avoid an obligation to pay the government. Under the amendment, neither a qui tam plaintiff nor the government has to show that the provider used a false statement to conceal this obligation. Rather, in order to be brought within the ambit of the FCA, it must only be shown that the claimant knowingly concealed the obligation. This occurs when the person has actual knowledge of the obligation or acts in "deliberate ignorance" or in "reckless



disregard” for the truth. The FERA also significantly expanded liability under the FCA by prohibiting a provider from “knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the government.” The net effect of the FERA amendments was to make a claimant liable for the *retention* of an overpayment, and no longer requiring an affirmative act in its furtherance.

PPACA

The latest amendment to the FCA came with the passage of PPACA, which continued the trend of increasing healthcare providers’ exposure to liability under the FCA. Section 6402(d) of PPACA expanded the scope of the FCA yet again to explicitly include Medicare and Medicaid overpayments as “obligations” within the meaning of the FCA. The drafting of the legislation left much to be desired, as many key aspects are undefined.

Ambiguities of “Reporting and Returning” Legislation

As a result of PPACA Section 6402(d), a healthcare provider that, for whatever reason, receives an overpayment may now be in jeopardy of violating the FCA. What could have been a simple billing error now has the potential to expose the provider to substantial monetary penalties. Turning to the substance of the law may leave the provider with material questions about overpayments and their return. Recently, though, CMS issued a proposed rule on overpayments in the February 16, 2012, *Federal Register*.⁶ While the proposed rule fills in some gaps, ambiguities remain.

What Is an Overpayment?

The proposed rule defines an overpayment as “. . . any funds a person receives or retains under title XVIII of the [Social Secu-

urity] Act to which the person, after applicable reconciliation, is not entitled under such title.”⁷ (The “applicable reconciliation” reference pertains to a cost-reporting provider and the rule clarifies that the only overpayments that may be delayed until the cost report is due are ones reconciled by the cost report.) The preamble in the regulation provides a number of examples of overpayments, and interestingly, they are identical to ones previously proposed in 1998 when the Centers for Medicare & Medicaid Services (CMS) attempted to amend Medicare regulations governing liability for overpayments.⁸ They include:

- Payments made by Medicare for non-covered services;
- Payments in excess of the allowable amount for an identified covered service;
- Errors and non-reimbursable expenditures in cost reports;
- Duplicate payments; and
- Medicare payment when another entity had the primary responsibility for the payment.

In spite of these examples, there is still ambiguity regarding what deems a provider as being “not entitled” to a payment. Neither the 1998 rule, nor the current proposed rule, have attempted to flesh out this term.

Identification of an Overpayment

Under PPACA, an overpayment must be reported and returned within sixty days from the date on which the overpayment was “identified,” or the date any corresponding cost report is due. The clarification of when an overpayment has been identified is important, as it is the triggering mechanism for the sixty-day timetable for reporting and returning the funds. It may be proffered that a spectrum of certainty exists regarding overpayments, ranging from a suspicion that one has occurred on one end, over to unmistakable knowledge that one has occurred on the other end. Providers and compliance officers must know at what point on the spectrum the law’s teeth take hold and the clock starts ticking.

The proposed rule states that a payment has been identified if a person “has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment.” This definition is meant to incentivize providers to exercise reasonable diligence in determining whether an overpayment has occurred. Without it, CMS reasons, some may avoid activities such as self-audits and compliance checks.

In the preamble of the proposed rule, CMS provided some examples of when an overpayment has been “identified” for purposes of the law:

- A provider reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.

- A provider learns that a patient death occurred prior to the service date on a claim that has been submitted for payment.
- A provider learns that services were provided by an unlicensed or excluded individual on its behalf.
- A provider performs an internal audit and discovers that overpayments exist.
- A provider is informed by a government agency of a potential overpayment, and the provider fails to make a reasonable inquiry.
- A provider experiences a significant increase in Medicare revenue for no apparent reason.

The proposed definition, along with the examples of overpayment identification, indicate an intent by the U.S. Department of Health and Human Services (HHS) to affix liability at a relatively early point on the spectrum described above. A provider who fails to conduct a reasonable inquiry after it learns of a potential overpayment, or who fails to conduct that inquiry in a timely manner, may have knowingly retained an overpayment. If adopted in its current form, the CMS rule will put to rest any doubt that some indicia of an overpayment will start the sixty-day clock. Nevertheless, certain situations could lead to a tit-for-tat argument between the government and providers about when the actual identification of the overpayment occurred. Also, the proposed rule sidesteps the fact that sixty days may not be a sufficient period of time for many providers to conduct a “reasonable inquiry” and determine the actual amount of the overpayment. This element is likely to be the subject of many comments on the proposed rule.

Erosion of Substantive Defenses

As if the ambiguities in the overpayment rules were not enough, a provider’s ability to defend itself against an alleged FCA violation has taken some hits. There are two common defenses to an FCA allegation, neither of which has emerged unscathed from the trend of increased liability. By all appearances, recent court decisions and PPACA provisions have eroded the effectiveness of FCA defenses, making it more difficult for a healthcare provider to defend against a claim of retention of an overpayment.

9(b) Motion

Historically, a viable defense to an alleged FCA violation is a motion to dismiss for failure to plead fraud with particularity under the Federal Rules of Civil Procedure Rule 9(b).⁹ To satisfy the Rule 9(b) standard, a plaintiff’s pleading must specify the “time, place, and substance of the defendant’s alleged conduct.”¹⁰ These details may be difficult to come by for a whistleblower in the healthcare setting, where evidence such as “observations and conversations” alone have been insufficient.¹¹ Instead, the pleading has been required to set forth, at the very least, the “who, what, when, where, and how of the alleged fraud.”¹² Some circuit courts have

gone as far as to require a qui tam relator to provide details such as the dates of the claims, content of the forms or bills, identification numbers, amount of money involved, the particular goods or services for which the government was billed, and the individuals involved.¹³ Motions to dismiss FCA claims have successfully used Rule 9(b) on several occasions.¹⁴

However, there is an increasing trend in recent circuit court decisions to interpret the Rule 9(b) particularity requirement differently in FCA cases.¹⁵ Under a relaxed standard, the qui tam plaintiff must only allege the details of a fraudulent *scheme*, rather than the details of the claims themselves.¹⁶ For example, in *U.S. ex rel. Grubbs v. Kanneganti*, a doctor brought a qui tam action against his physician colleagues and hospital employer. He alleged the physicians billed Medicare and Medicaid for face-to-face visits when they actually only met with nursing staff. The Fifth Circuit held that the plaintiff did not necessarily need the exact dollar amounts, billing numbers, or dates to prove by a preponderance that fraudulent bills were actually submitted for payment.¹⁷

This lowering of the pleading bar may allow future whistleblowers the luxury of relying on generalities regarding an alleged fraudulent practice and eliminate the need for plaintiffs to have access to the details of the overpayment.

Public Disclosure Bar

A healthcare provider facing a charge of impermissibly retaining an overpayment has a second defense available. A qui tam action brought under the PPACA’s overpayment provision could be susceptible to a proper 12(b)(6) motion via the “public disclosure bar” of the FCA.¹⁸ Congress added the public disclosure bar to the FCA in 1986 as a way of weeding out “parasitic lawsuits”—ones based on information that had been previously disclosed in public, either in the news media or in a governmental investiga-



tion or hearing. The rule operated to ensure whistleblower suits under the FCA were based on fresh information regarding allegations of previously unknown fraud.

PPACA, however, has dealt several blows to the public disclosure defense. First, PPACA explicitly limited “public disclosures” to federal proceedings and reports, effectively nullifying a 2010 Supreme Court decision.¹⁹ That case—*Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*—expanded the scope of the public disclosure bar to include state and local proceedings and reports. But PPACA has narrowed the scope to allegations disclosed only in the news media or a “congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation.” This rule not only excludes allegations disclosed in a state proceeding, but impliedly excludes disclosures that occur during private litigation as well. Thus, the public disclosure bar is only implicated if a disclosure occurs in a federal proceeding or makes its way into the media.

Secondly, even if a disclosure has occurred in a federal proceeding, PPACA gives DOJ the opportunity to oppose a defendant’s motion to dismiss. The language of the statute requires the court to dismiss the action when a disclosure in a federal proceeding has occurred, “unless opposed by the Government.” This gives DOJ a crucial role to play in allowing a qui tam suit to proceed where it otherwise would have been dismissed because of a public disclosure.

Lastly, by altering the exception to the public disclosure bar, PPACA has made it markedly easier for a private party to bring a qui tam suit. Prior to the Act, those relators who were an “original source” of the information could proceed with their

claim, despite a public disclosure. However, the relator must have possessed “direct and independent” knowledge of the claim. PPACA amended this by eliminating the “direct and independent” knowledge test and replacing it with a two-pronged alternative. Either: (1) the individual voluntarily disclosed the information to the government prior to the public disclosure; or (2) the individual possess information that materially adds to the publicly disclosed allegations.

It is unclear at this point what type of information would “materially add” to the public allegations, or even how much information is required to render it material. What is known is that the public disclosure bar no longer ensures that qui tam plaintiffs are true whistleblowers. The “original source” amendment casts a wide net in terms of who may qualify as a whistleblower and opens the door for those without firsthand knowledge of an overpayment to bring a qui tam action. This combined with the less-stringent pleading standards show that the landscape for qui tam plaintiffs in health-care fraud suits is becoming demonstrably more favorable.

Raising the Stakes: Implications for Healthcare Providers

The possible implications of Section 6402(d)’s “Reporting and Returning of Overpayments” extend beyond fines and penalties under the FCA.

Medicare and Medicaid Exclusions Under the “Responsible Corporate Officer” Doctrine

Under the responsible corporate officer doctrine, an officer may be liable for civil and criminal penalties where the officer participates in corporate wrongdoing, knowingly approves of wrongful conduct, or was in a position to prevent the wrongdoing, but failed to do so. In March 2011, the HHS Inspector General testified before Congress regarding the efforts of HHS to combat waste, fraud, and abuse in Medicare and Medicaid. The Inspector General testified that the Office of Inspector General (OIG) is targeting enforcement at individual leaders within the healthcare industry and is increasingly seeking to punish those in positions of responsibility within the organizations.

Punishment for Medicare or Medicaid fraud usually involves excluding the individual from the programs for three years. However, HHS recently imposed a twelve-year exclusion on three pharmaceutical executives charged with misdemeanor drug misbranding. The unusually severe penalties were upheld in federal district court and will likely end the pharmaceutical careers of the three executives.²⁰

The severity of recent penalties under the responsible corporate officer doctrine, coupled with the Inspector General’s expressed intent to punish corporate fraud on the individual officer level, is evidence that reducing fraud and abuse is a priority of the OIG. One need look no further than the “Reporting and Returning of





Overpayments” provision of PPACA to recognize that dealing with overpayments is a centerpiece of that effort. This will require heightened vigilance on the part of healthcare executives. The failure to systematically, promptly, and consistently identify overpayments could result in personal, career-ending consequences, in addition to liabilities under FCA.

Whistleblower Actions

The upshot of the more-lenient standard for Rule 9(b) motions and the relaxed interpretation of the public disclosure bar is the possibility for an increase in whistleblower actions. Where a whistleblower might once have been precluded from bringing a qui tam action for lack of knowledge of the particulars of the overpayment, or by a previous disclosure in a state proceeding or private litigation, the whistleblower now faces few obstacles. And during an economic downturn, the lure of a share in the recovery might prove quite tempting to pursue.

Conclusion

PPACA Section 6402(d) is a small provision, but it will almost certainly have important and far-reaching implications for the healthcare industry. Like many laws, it features ambiguities that may lead to misinterpretation and confusion. Defenses to allegations of FCA violations have been eroded, and exposure for corporate officers and for providers to whistleblower actions have increased. In addition, in the proposed overpayment rule, CMS is now pushing for a ten-year look-back period by amending the current regulations that typically result in a four-year period. Therefore, healthcare providers would do well to remain vigilant for overpayments, know the rules, and timely act to mitigate the associated risks. Otherwise, unless some FCA cases involving

overpayments proceed to trial and the courts provide some interpretations that afford relief for defendants, it appears the proverbial deck now is somewhat stacked against providers.

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- 1 Press Release, U.S. Department of Justice, Justice Department Recovers \$3 Billion in False Claims Act Cases in Fiscal Year 2011 (Dec. 19, 2011).
- 2 Kelly Kennedy, *Medicare fraud sting results in 91 arrests nationwide*, USA Today, Sept. 7, 2011.
- 3 31 U.S.C. §3729-3733.
- 4 President Barack Obama, Remarks to a Joint Session of Congress (Sept. 9, 2009) (“We’ve estimated that most of this [health care reform] plan can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse”).
- 5 Fraud Enforcement and Recovery Act, 31 U.S.C. § 3729 (2009).
- 6 77 Fed. Reg. 9179 (Feb. 16, 2012).
- 7 The proposed definition only references the Medicare program because CMS has indicated in the preamble to the proposed rule that, at this time, it is proposing to implement the overpayment requirements only as they relate to Medicare Part A and Part B providers and suppliers. CMS indicates that “other stakeholders” will be addressed at a later date.
- 8 Medicare Program; “Without Fault” and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability, 63 Fed. Reg. 14506, 14517 (March 25, 1998).
- 9 Fed. R. Civ. P. 9(b).
- 10 *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 149 F.3d 227, 234 (3d Cir. 1998).
- 11 *Gublo v. NocaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass 1999).
- 12 *Id.*
- 13 *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220 (1st Cir. 2004).
- 14 See *U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Laboratories, Inc.*, 2000 WL 17838 (E.D. La. 2000); *U.S. ex rel. Cox v. Iowa Health System*, 29 F. Supp. 2d 1022 (S.D. Iowa 1998); *U.S. ex rel. Butler v. Magellan Health Services, Inc.*, 74 F. Supp. 2d 1201 (M.D. Fla. 1999).
- 15 See *U.S. ex rel. Duxbury v. Ortho*, 579 F.3d 13; also see *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180.
- 16 *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (Higginbotham, J.) (“To require these details [time, place, contents, identity] at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates.”).
- 17 *Id.* at 190.
- 18 31 U.S.C. § 3730(e)(4)(2010).
- 19 *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, 130 S. Ct. 1396 (2010), *abrogating United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734 (3rd Cir. 1997).
- 20 *Friedman v. Sebelius*, 755 F. Supp. 2d 98 (D.D.C. 2010).

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