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PQRS and its Penumbra

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PQRS and its Penumbra

“If you cannot measure it, you cannot improve it.”

- William Thomson, 1st Baron Kelvin.

.1 Introduction

The measuring and improvement of quality continues to be a central issue in health care. As part of its ongoing efforts to bring quality metrics to bear in the federal health care system, the Centers for Medicare and Medicaid Services (CMS) have spent the last several years deploying a variety of initiatives to track quality data. In recent years, many of those initiatives have transformed into permanent programs, which now not only track quality information, but also use this information as the basis for additional payments or imposing penalties on health care providers. At the same time, new programs are being developed and will begin in the coming years. As part of this constellation of quality-tracking programs, the Physician Quality Reporting System is a key tool in CMS' efforts to measure the quality of care delivered by physicians who participate in Medicare, but it sits within a range of related programs.

To complicate matters further, these various systems often overlap, potentially leading to uncertainty and confusion for physicians participating in the measure-reporting process. It is important for physicians and their counsel to understand what must be reported, how to report, where the systems themselves overlap, the implications of that overlap, and how the information itself is used. Physicians and other providers not only face payment penalties for failing to report or improperly reporting, they also face the consequences of much of this data being displayed to the public on government websites.

This chapter examines these issues from both a legal and practical perspective. It explores the implications of inaccurate or improper reporting, as well as not reporting at

all. Although the chapter's primary focus is on the experience of physicians and small physician groups (as well as other eligible providers), for context it also addresses briefly programs affecting hospitals and other institutional providers. Given the federal government's more rapid development of quality-measurement systems which apply to these providers, an understanding of how these programs have developed and currently function can offer insight as to the ultimate direction that will be taken with similar physician-oriented programs.

2 The Physician Landscape

Since its inception, the Medicare system has paid physicians primarily on the basis of volume of services (fee for services). The more services a physician performs and bills for, the more money the physician makes. The only quality-oriented element of this payment structure was, arguably, the issue of medical necessity as applied to whether a claim would be paid. Facing a demographic and economic maelstrom with retiring Baby Boomers and a struggling economy, CMS has recognized that this payment model cannot be sustained indefinitely, and is changing how it pays for services in fundamental ways.

"Given that CMS policies have a transformative impact on the health care system, it is important to develop the tools necessary to create rational approaches to lessen healthcare cost growth and to identify and encourage care delivery patterns that are not only high quality, but also cost-efficient. To help address these concerns, CMS...has begun to transform itself from a passive payer of services into an active purchaser of higher quality, affordable care. Further future efforts to link payment to the quality and efficiency of care provided, would shift Medicare away from paying providers based solely on their volume of services. The catalyst for such change would be grounded in the creation of appropriate incentives encouraging all healthcare providers to deliver higher quality care at lower total costs."¹

¹ CMS Roadmap for Implementing Value Driven Healthcare in the Traditional Medicare Fee-for-Service Program, p. 1.

Towards this end, CMS has deployed and is in the process of developing, a broad range of quality-oriented programs applicable to both physicians and hospitals. These programs incentivize reporting of quality data, and in some cases improved performance of services.

2.1 Physician Quality Reporting System

The Physician Quality Reporting System began as the Physician Quality Reporting Initiative (PQRI) in late 2007. At its inception, the initiative merely rewarded physicians with an additional 2% of Medicare reimbursements for reporting certain data relating to quality. The data was not initially used for any additional purpose; it was simply collected. In 2008, the initiative was modified to split out its electronic prescribing measure into a separate system of its own (discussed below). However, PQRI (and later PQRS) was primarily concerned with the act of reporting itself, rather than the level of quality indicated by the reported data; reporting physicians were given incentive payments regardless of whether the data reported indicated poor quality or good quality. The system incorporated neither the proverbial carrot nor the stick with respect to the actual quality of the services reported. CMS has explicitly stated that PQRS does not measure the quality of performance, but rather tracks the reporting of the quality measures collected.²

With the passage of the Patient Protection and Affordable Care Act of 2010 (ACA), PQRI changed from an initiative to a full-fledged system, and was renamed accordingly.³ While both bonuses and penalties were part of the original initiative, the

² See, Medicare Physician Fee Schedule Final Rule, 76 Fed. Reg. 73426, November 28, 2011.

³ Patient Protection and Affordable Care Act of 2010, section 10327. See also, 42 CFR § 414.90.

new PQRS has modified them. Under the current system, for the reporting periods for 2012 through 2014, eligible providers (or "EPs," which includes physicians) may earn a bonus of 0.5% of their Medicare Part-B reimbursement. They may, however, earn an additional 0.5% bonus if they meet certain additional requirements.⁴ In 2013, PQRS becomes a hybrid of bonuses and "payment adjustments" (in actuality, punitive deductions). In 2015, PQRS will become purely punitive and will deduct 1.5% of the EP's Medicare Part-B reimbursement for failure to effectively participate, with the deduction increasing to 2.0% in 2016.

Participation in the program itself is not mandatory. However, former CMS Administrator Donald Berwick, M.D. has stated, "Although participation in our pay-for-reporting programs is optional now, it should be regarded as imperative in terms of medical professionals' shared goal of improving quality of care and patient safety."⁵ In essence, given the potential "payment adjustments," physicians should treat PQRS and its associated programs as "strongly recommended," if not mandatory.

The system itself is open to all eligible physicians and non-physician practitioners (NPPs) submitting Medicare Part-B claims.⁶ No enrollment is required, as long as the

⁴ The EP must submit for a full year, rather than for a 6-month reporting period; the data must be submitted by a "Maintenance of Certification program" -- such as a program run by specialty boards which itself includes an educational component and certification assessment component -- which is functioning as a registry; and the EP must also participate in a certification program each year and more frequently than is required to maintain board certification status. 42 CFR § 414.90. For further discussion of the current Maintenance of Certification Program Incentive, see 76 Fed. Reg. 73385-73389, November 28, 2011.

⁵ "CMS Shows Gains in Key Quality Indicators Through Physician Quality Reporting System and E-Prescribing Incentive Program," Donald Berwick, M.D., CMS Press Release, April 19, 2011. <http://www.cms.gov/apps/media/press/release.asp?Counter=3937&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>.

⁶ The definition of "eligible practitioners" includes: doctors of medicine, osteopathy, podiatric medicine, optometry, dentistry, oral surgery, and chiropractic) and non-physician practitioners (defined to include

physician already participates in Medicare.⁷ The data itself must be reported in the required manner (discussed more fully below). There is also an option for physician groups to participate.

The quality measures themselves are reported based on a denominator, such as a total number of patients treated by a physician, and a numerator such as the number of patients with a specific condition. As of this writing, there are over 200 different measures, although measures may be added, removed, or modified.⁸ There are four primary methods of reporting under PQRS: (1) claims-based reporting, (2) registry-based reporting,⁹ (3) reporting using an electronic health record (EHR) or through an "EHR data submission vendor"¹⁰, and (4) group reporting.

physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, certified nurse midwives, clinical social workers, clinical psychologists, registered dietitians, nutritional professionals, audiologists, physical therapists, occupational therapists, and qualified speech-language therapists. 42 CFR § 414.90.

⁷ For more information on the Medicare enrollment process, see Shay, "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?", HEALTH LAW HANDBOOK (2009 ed.); Shay, "Halt! Who Goes There?: Coping with the Continuing Crackdown on Medicare Enrollment", HEALTH LAW HANDBOOK (2011 ed.) West Group. Non-participating physicians are not eligible, even if they accept assignment of claims.

⁸ For the full list of measures for 2012 reporting using claims-based or registry-based reporting, see 76 Fed. Reg. 73350-73362, November 28, 2011. For measures for the 2012 reporting period available for EHR-based reporting, see 76 Fed. Reg. 73364-73366, November 28, 2011. For measures for the 2012 reporting period available for the Group Practice Reporting Option, see 76 Fed. Reg. 73384-73385, November 28, 2011.

⁹ The regulations describe a registry as a "data submission vendor." 42 CFR § 414.90. Registries collect data from participating EPs, and submit it to CMS on the EPs' behalf. They function as HIPAA business associates. 76 Fed. Reg. 73319, November 28, 2011. Submission through registries does pose a risk, however. CMS has stated that "Even though a registry is listed as "qualified," we cannot guarantee or assume responsibility for the registry's successful submission of the required [PQRS] quality measures results or measures groups results or data elements submitted on behalf of a given [EP]." 76 Fed. Reg. 73321-73322, November 28, 2011.

¹⁰ This new category for submitting data can include registries, EHR vendors, and other entities that can receive and transmit clinical quality data extracted from an EHR. As with registries, CMS warns of its inability to guarantee that such an EHR data submission vendor will successfully submit the data. 76 Fed. Reg. 73324, November 28, 2011.

In claims-based reporting, the physician reports on individual claims as he or she normally would, but also reports a "quality data code" (also known as a "quality measure code" or a "QDC"). To participate successfully, an EP must report on 50% or more of applicable Medicare Part-B patients for at least three individual measures; or must report on each measure if fewer than three measures apply to the EP's practice. Alternatively, the EP may report in measure groups where multiple individual measures for a specific condition or treatment, such as asthma or preventive care, are reported. When reporting measure groups, the EP must report on 50% or more of no fewer than eight patients for a specific group. For either approach, EPs must report for a twelve-month period.¹¹

In registry-based reporting by individual EPs, a registry reports the QDCs on behalf of the EP, based on data that the EP submits to the registry. The EP must submit data on at least three PQRS measures, and report each measure on at least 80% of the EP's Medicare Part-B seen during the reporting period to whom the measure applies. As with claims-based reporting, the reporting period is a 12-month period. With EHR reporting, the EP must use a "qualified EHR,"¹² and the reporting period is a 12-month period.

¹¹ In previous years, a six-month reporting period was offered as an option. Beginning in 2012, however, the six-month reporting period has been eliminated. In explaining its rationale for eliminating the six-month reporting period for claims-based and registry-based reporting, CMS stated "We [previously] retained the 6-month reporting option to encourage participation in the program. 2012 will mark the 6th year of [PQRS]. We believe that eligible professionals have had ample time to familiarize themselves with the program and its requirements. Therefore, we believe our desire to streamline the program, align our reporting periods with other various CMS programs, and collect more meaningful data outweighs stakeholders' desire to retain the 6-month reporting period we are eliminating." 76 Fed. Reg. 73318, November 28, 2011.

¹² The definition of a "qualified EHR" is not identical to that used by the "Meaningful Use" program, discussed below. CMS is aware of the difficulties this poses, but has stated "At this time, it is not technically feasible to automatically qualify Certified EHR Technology to report 2012 Physician Quality Reporting System measures," but states that they are exploring ways to align PQRS and "Meaningful Use" in the future. 76 Fed. Reg. 73323, November 28, 2011. Instead, for 2012, CMS intends to create a list of

Group practice¹³ reporting also has a 12-month reporting period. Payment under the group practice reporting option is mutually exclusive with payment to the individual reporting EP. Therefore, EPs who reassign their right to payment to a group which itself participates through the group-reporting measure cannot be paid individually for their own reporting.

Beginning in 2015, a failure to properly report (or failure to report at all) results in a "payment adjustment," the percentage of which will vary from year to year.¹⁴ Data submitted using multiple reporting mechanisms also is not combined to determine incentive eligibility.¹⁵ Interestingly, the data on which the 2015 payment adjustment will be applied is the data reported by EPs in 2013. In response to a comment suggesting that the reporting period for the 2015 payment adjustment should mirror the reporting periods for the incentive payments, CMS explained,

“We considered using a CY 2014 and CY 2015 reporting period for the 2015 payment adjustment. However, it is not operationally feasible to create a full calendar year reporting period for the 2015 payment adjustment any later than CY 2013 and still avoid retroactive payments or the reprocessing of claims. Therefore, using 2015 as an example, we believe it is necessary to reduce the PFS amounts concurrently for PFS allowed charges for covered professional services furnished in 2015. If we do not reduce the PFS amounts concurrently with claims submissions in 2015, we would need to potentially recoup or provide added payments after the determination is made about whether the payment

EHR vendors who are qualified under PQRS to indicate which vendors' products have also received a certification under "Meaningful Use." 76 Fed. Reg. 73323, November 28, 2011.

¹³ The 2012 Medicare Physician Fee Schedule changed the definition of a "group practice" for PQRS purposes. Now, only group practices with twenty-five or more physicians may participate in the GPRO. 76 Fed. Reg. 73315, November 28, 2011. 42 CFR § 414.90(b). The 2012 Medicare Physician Fee Schedule also discontinued a previous version of the group practice reporting option for smaller group practices. In future years, CMS has indicated that it may reinstate an option for smaller groups to report as groups rather than as individual EPs.

¹⁴ In 2015, EPs who fail to properly submit will only receive 98.5% of their fee schedule amount for services furnished during the year. In 2016 and for subsequent years, the applicable percentage is 98.0%. 76 Fed. Reg. 73391, November 28, 2011. At that time, incentive payments for reporting will also cease.

¹⁵ 76 Fed. Reg. 73318, November 28, 2011.

adjustment applies, or alternatively, hold claims until such a determination is made.¹⁶

In other words, CMS will determine, based on data reported in 2013, whether the 2015 payment adjustment applies. If it applies a payment adjustment, CMS will reduce *concurrent* payments in 2015 for claims submitted in 2015, rather than apply the payment adjustment retroactively and have to "chase the money" by recouping payments. This, at least, means that the payment adjustments will not implicate the "overpayment" provisions of the federal False Claims Act.¹⁷

The system currently has no hardship exceptions -- a "payment adjustment" will be applied even if the EP cannot or does not participate due to circumstances beyond their control. The system also provides feedback reports on an annual basis and, beginning in 2012, provides "interim feedback reports." The final feedback report is provided only after the EPs have already submitted their data. Interim feedback reports are "simplified versions of the feedback reports we currently provide," and are issued in the summer of the respective program year.¹⁸ Even so, such limited periodic feedback offers EPs relatively little opportunity to correct reporting errors or track their progress.¹⁹

¹⁶ 76 Fed. Reg. 73391-73392, November 28, 2011.

¹⁷ Discussed more fully in Section 4.1 below.

¹⁸ 76 Fed. Reg. 73390, November 28, 2011. However, the form and content of the interim feedback reports is, at the time of this writing, in development. CMS has indicated that future program years will allow for the public to provide suggestions regarding the form and content of such reports. 76 Fed. Reg. 73390, November 28, 2011. Moreover, these interim reports will only be available for those EPs who submit data using the claims-based reporting mechanism.

¹⁹ In response to commentary suggesting that interim feedback reports be made available for those EPs who report using registries or EHRs, CMS stated "since we do not receive data from the registry and EHR reporting mechanisms until the following calendar year, it is not technically feasible for us to develop interim feedback reports that provide reporting performance related to registry and/or EHR-based reporting. However, as stated in *[sic]* previously in section VI.F.1.d, we are finalizing our proposal to require registries and EHR vendors to provide such feedback reports, if technically feasible." 76 Fed. Reg. 73390, November 28, 2011.

The problem of after-the-fact feedback is compounded by limitations on appealing or reviewing CMS' negative determination of successful participation. The regulations themselves explicitly prevent EPs from appealing for administrative or judicial review of the determinations of which measures apply to services provided by an EP, payment limitations, or the applicability of either an incentive payment or a payment adjustment.²⁰ An "informal review" may be requested, however, if the EP feels that a determination that it failed to meet the PQRS submission requirements was made in error.²¹ The request must be submitted in writing or through email within ninety days of the posting of feedback reports. CMS will respond to the EP's request within ninety days of receipt, and the decision (based on an informal review) is final -- there is no further appeal or review after this one request. As an informal review, the process also does *not* include a hearing or evidence submission process, although EPs are permitted to submit information to assist in the review.²²

2.2 E-Prescribing Incentive System

The E-Prescribing Incentive System (hereinafter "ERx") was originally a PQRI measure in the initial phases of PQRI. However, with the passage of the Medicare Improvement for Patients and Providers Act of 2008, the ERx system became a separate

²⁰ 42 CFR § 414.90(h).

²¹ 42 CFR § 414.90(i).

²² 76 Fed. Reg. 73390-73391, November 28, 2011. Originally, the response window was set at 60 days. However, CMS later extended this to 90 days. In response to comments requesting that the response period remain 60 days in the 2012 Medicare Physician Fee Schedule, CMS stated that it was retaining the 90 day response window because "we anticipate a higher volume of requests for informal review, particularly as we move towards the 2015 payment adjustment and continue to align with various CMS programs to encourage participation in the Physician Quality Reporting System." 76 Fed. Reg. 73391, November 28, 2011.

program.²³ In explaining the need for a separate system, CMS stated that the ERx program was adopted, "Because of ERx's proven potential to reduce medication errors and the cost of medical care..."²⁴ CMS has further described the purpose of the ERx program, especially for 2012 and beyond, as being "to continue to encourage significant expansion of electronic prescribing by authorizing a combination of financial incentives and payment adjustments."²⁵ However, as with PQRS, CMS has made it clear that, "The main purpose of having eligible professionals report on the electronic prescribing measure is to ensure electronic prescribing systems are being utilized, not to collect data."²⁶

The ERx program is available to "eligible professionals," which includes physicians and certain NPPs,²⁷ and also includes a group practice reporting option. For the 2012 reporting period²⁸, successful EPs are awarded a bonus of 1.0% of their Medicare Part-B reimbursement, with the incentive payment dropping to 0.5% in 2013. Beginning in 2012, if an EP fails to successfully report, a payment adjustment of 1.5% is applied to their Medicare Part-B reimbursement for the 2012 reporting period. The payment adjustment increases to 2.0% for 2013 and subsequent reporting periods. For 2012 only, the payment adjustment will not apply to: (1) EPs who are not physicians

²³ Medicare Improvements for Patients and Providers Act of 2008, Section 132. The ERx program was formally launched on January 1, 2009.

²⁴ 2011 Electronic Prescribing Incentive Program -- Adoption/Use of Medication Electronic Prescribing Measure. Available at www.cms.gov/ERxIncentive/06_E-Prescribing_Measure.asp.

²⁵ 76 Fed. Reg. 73392, November 28, 2011.

²⁶ 76 Fed. Reg. 73396, November 28, 2011.

²⁷ For a full list, see http://www.cms.gov/ERxIncentive/05_Eligible_Professionals.asp.

²⁸ The 2012 reporting period is the full calendar year for 2012.

under Medicare; (2) EPs with fewer than 100 cases with an encounter code that meets the denominators; or (3) EPs who successfully reported during the period between January 1, 2011 and June 30, 2011.²⁹

The ERx system also uses denominators and numerators.³⁰ However, under ERx, the denominators are CPT codes, while the numerator is a "Gö" code indicating that at least one prescription during the encounter was generated and transmitted electronically using a "qualified system."³¹ The definition of a "qualified EHR" as well as that of a "qualified registry" under ERx mirror PQRS,³² as do the reporting methods for ERx: claims-based reporting, registry-based reporting, and EHR-based reporting, as well as a group practice reporting option.³³ Note, however, that this is distinct from reporting for incentive payments in 2012 and 2013.

Unlike PQRS, however, the ERx system includes "hardship exceptions," and a process by which such exceptions are claimed, to avoid the imposition of the payment adjustment. An exception may be claimed when an EP cannot participate: (1) due to state

²⁹ 75 Fed. Reg. 73562, November 29, 2010.

³⁰ There is also an option for reporting using Medicare Part-D electronic prescribing standards. For more information on this reporting approach, see CMS's discussion in the 2012 Medicare Physician Fee Schedule beginning at 76 Fed. Reg. 73398, November 28, 2011.

³¹ The full list of denominator codes is: 90801, 90802, 90804, 90805, 90806, 90807, 90808, 90809, 90862, 92002, 92004, 92012, 92014, 96150, 96151, 96152, 99201, 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 304, 99305, 99306, 99307, 99308, 99309, 99310, 99315, 99316, 99324, 99325, 99327, 99328, 99334, 99335, 99336, 99337, 99341, 99342, 99343, 99344, 99345, 99347, 99348, 99349, 99350, G0101, G0108, and G0109. The numerator "Gö" code is G8553. 76 Fed. Reg. 73398, November 28, 2011.

³² See, 42 CFR § 414.92(b), which references the PQRS definitions at 42 CFR § 414.90.

³³ The definition of a "group practice" for ERx purposes is identical to that used in the PQRS program, thus a "group practice" is a group or single tax identification number of at least 25 EPs. 76 Fed. Reg. 73394, November 28, 2011. In addition, groups which participate in ERx as group practices, must also participate in PQRS as group practices, although a this is only a *participation* requirement; the group need not *successfully* report as a group under PQRS in order to *participate* in the ERx group reporting option. 76 Fed. Reg. 73395, November 28, 2011.

law restrictions (such as state laws prohibiting the prescription of narcotics using electronic methods); (2) when the EP is in a rural area with limited high-speed internet access; (3) when the EP is in an area with limited pharmacies available to fill electronic prescriptions; (4) if the EP participates in the “Meaningful Use” program (although this requires more than mere intent to participate); (5) when the EP has limited prescribing activity in the first place; (6) or where the EP has insufficient opportunities to report due to limitations of the measure’s denominator.³⁴

In addition, CMS retains the option to determine that (A) the incentive payment will be limited, and/or (B) the payment adjustment will not apply. If the EP’s charges for prescribing activity accounts for less than 10% of the EP’s total Medicare Part B allowed charges, the incentive will not be paid, even though the EP otherwise successfully participates.³⁵ Moreover, the reporting requirements to be a successful prescriber under the incentive payment system, and to be a successful prescriber under the payment adjustment system are not identical. For example, for individual EPs submitting using claims-based reporting for the 2013 incentive payment, the EP must report the electronic prescribing measure’s numerator for at least 25 unique denominator-eligible visits.³⁶ By contrast, to avoid a payment adjustment when reporting for the six-month reporting period in 2013,³⁷ the EP need only report one prescription for Medicare Part-B patients was created during an encounter and was generated and transmitted electronically using a

³⁴ For example, where the EP is a surgeon who prescribes post-operative drugs to a patient on a day later than the date of the surgery itself.

³⁵ CMS may also opt not to pay the incentive when the EP submits a sufficient number of prescriptions under Medicare Part-D. 76 Fed. Reg. 73403, November 28, 2011.

³⁶ 76 Fed. Reg. 73405, November 28, 2011.

³⁷ Between January 1, 2012 and July 30, 2012. 76 Fed. Reg. 73396, November 28, 2011.

qualified electronic prescribing system at least ten times; the visit need not be a denominator-eligible visit.³⁸

As an additional wrinkle in the ERx payment adjustment system, the reporting periods are not identical to the ERx incentive payments, nor are the requirements for satisfactory reporting identical. In the 2011 Medicare Physician Fee Schedule, CMS finalized a six-month reporting period for the 2012 payment adjustment³⁹ and a twelve-month reporting period for the 2013 payment adjustment for both individual EPs and groups.⁴⁰ The 2012 Medicare Physician Fee Schedule added new reporting periods for the 2013 and 2014 payment adjustments. For the 2013 payment adjustment, an additional six-month reporting period was added.⁴¹ For the 2014 payment adjustment, a twelve-month reporting period was added for individual EPs, and a six-month period was added for individual EPs and groups.⁴²

Although ERx does include mechanisms for EPs to avoid the application of the payment adjustment, there are still lurking issues, similar to those found in PQRS. For example, the language of the federal regulations prohibits double payments for both individual EPs and groups.⁴³ If the EP reassigns the right to payment to a group that uses the group reporting option, the EP is no longer eligible for individual incentive payments.

³⁸ 76 Fed. Reg. 73408, November 28, 2011.

³⁹ Between January 1, 2011, and June 30, 2011. 76 Fed. Reg. 73395, November 28, 2011.

⁴⁰ Between January 1, 2011 and December 31, 2011. 76 Fed. Reg. 73395-73396, November 28, 2011.

⁴¹ 76 Fed. Reg. 73396, November 28, 2011[?]

⁴² Between January 1, 2013 and December 31, 2013; and, between January 1, 2013 and July 30, 2013, respectively. 76 Fed. Reg. 73396, November 28, 2011.

⁴³ See, 42 CFR § 414.92(e)(2).

However, the regulations are unclear as to how the payment adjustment will apply. For example, if an EP could satisfactorily report as an individual, but is also a member of a group which itself fails to successfully report, will the payment adjustment apply? Could the EP still opt to participate as an individual and meet the requirements as a safeguard against the group's failure to effectively report, or would doing so be problematic due to the prohibition against double incentive payments? The regulations do not say, but one can assume that such an approach would be operationally precluded because it could generate double payments.

Also of note is the fact that, while the EP cannot receive a bonus for participating in both ERx and "Meaningful Use," there is currently no hardship exception for "Meaningful Use" participation after the 2012 reporting period. In other words, an EP who participates in both "Meaningful Use" and ERx will certainly be precluded from receiving both bonuses, but may still be subject to the payment adjustment under ERx for failing to successfully report. At the same time, however, CMS has aligned the definition of a "qualified" electronic prescribing system to include EHR technology certified for "Meaningful Use."⁴⁴

The regulations are also vague on how, when, and where information will be published regarding successful EPs and groups; they simply state "CMS will post on a public Web site, in an easily understandable format, a list of the names of eligible professionals who are successful electronic prescribers."⁴⁵ As with PQRS, however, this information merely indicates who successfully prescribed. It does not provide

⁴⁴ 76 Fed. Reg. 73399, November 28, 2011.

⁴⁵ 42 CFR § 414.92(f).

concurrent feedback to allow EPs to adjust their reporting. It offers no notice if, for example, the EP's electronic prescribing software has lost its qualified status, if the EP's connection to a registry is faulty and the registry has not received claims, or if the EP's registry itself is not effectively communicating with CMS. Those who elect to participate in these programs must fly blind and hope for the best.

2.3 Meaningful Use

Also known as the Electronic Health Records Incentive Program, the "Meaningful Use" program incentivizes the adoption of electronic health record software (EHRs). Eligible professionals can obtain up to \$44,000 if they qualify as "meaningful users" of certified EHR software. One aspect of being a "meaningful user" is the reporting of data, some of which includes certain quality measures. These measures include, for example, computerized physician order entry; having drug-drug and drug-allergy interaction checks; maintaining active medication and medication allergy lists; generating and transmitting electronic prescriptions; recording smoking status; reporting ambulatory clinical quality measures (known as "CQMs") to CMS; and implementing drug formulary checks.⁴⁶ Currently, these measures are reported using an attestation method.⁴⁷

These measures can overlap with both PQRS and the ERx systems. With respect to PQRS, both programs use similar CQMs. For example, both allow for reporting of adult weight screening and follow-ups; and, influenza immunizations for patients fifty years or older. Both the ERx program and "Meaningful Use" require the generation and

⁴⁶ For the full list of CQMs for the 2011 and 2012 reporting years, see 75 Fed. Reg. 44398-44408, July 28, 2010.

⁴⁷ For information on how attestation may be made, see 42 CFR 495.8(a)(2).

transmission of electronic subscriptions. Likewise, both programs require similar software functionality to qualify.

However, EPs cannot simultaneously receive bonuses from both the ERx program and the "Meaningful Use" program. Moreover, EPs can only avoid the "payment adjustment" under the ERx program by participating in "Meaningful Use" during 2012. There is, confusingly, no similar prohibition on receiving payment incentives for participation in both PQRS and "Meaningful Use," nor is there any hardship exception for PQRS if an EP participates in "Meaningful Use." Lastly, it remains unclear what will happen if a physician participates as a member of a group in ERx, and also attempts to participate as an individual EP for "Meaningful Use" purposes. The language of the regulations suggests that the physician would be ineligible to receive his EP payment incentive under "Meaningful Use," but there is no independent confirmation of this fact. Physicians and physician groups will therefore need to carefully consider the programs in which they will simultaneously participate, and may want to evaluate whether it makes more financial sense to participate in PQRS and ERx, or PQRS and Meaningful Use.

2.4 Physician Value Based Purchasing

The Physician Value Based Purchasing (VBP) program is a new program created with the passage of the ACA, which will be fully implemented in 2015, which will pay physicians differentially under the Medicare Physician Fee Schedule, depending first on their quality performance and later on their quality and efficiency. The program, still very much in its infancy, will draw its data from measures reported under PQRS and "Meaningful Use."⁴⁸ The full list of proposed measures includes: (1) the measures in the

⁴⁸ 76 Fed. Reg. 73427, November 28, 2011.

core set of the 2012 PQRS; (2) all measures in the Group Practice Reporting Option of the 2012 PQRS; (3) the core measures, alternate core, and 38 additional measures in the 2012 "Meaningful Use" program.⁴⁹ CMS has articulated its reasons for using these measures, explaining that doing so "would reduce program inconsistencies, and reduce the reporting burden on physicians."⁵⁰

The data reported under these programs will be compared against a "value modifier," which itself will be determined based on total per capita cost measures and per capita cost measures for beneficiaries with four specific chronic conditions.⁵¹ In explaining its reasoning for adopting these criteria for the "value modifier," CMS states that it believes these measures "are useful overall measures of the volume of health care services to beneficiaries. In addition, the chronic disease categories can provide information on the volume of care provided to patients suffering such conditions."⁵² These measures will be risk-adjusted without regard to existing geographic modifiers, "to ensure [CMS compares] Medicare payments on an 'apples-to-apples' basis."⁵³ The episode grouper combines separate but clinically related items and services into a single

⁴⁹ For the complete list of measures for individual physicians and for groups, see 76 Fed. Reg. 73429-73432, November 28, 2011.

⁵⁰ 76 Fed. Reg. 73432, November 28, 2011. CMS has indicated that it will not, however, use administrative claims-based measures derived from the individual 2010 Physician Feedback Program reports in its value modifier, nor will it use care-coordination/transition measures. 76 Fed. Reg. 73432-73433, November 28, 2011.

⁵¹ The chronic conditions are: COPD, heart failure, coronary artery disease, and diabetes. 76 Fed. Reg. 73434, November 28, 2011.

⁵² 76 Fed. Reg. 73434, November 28, 2011.

⁵³ CMS intends to host public events to gather additional input on the value modifier and explain its price standardization and risk adjustment methodologies. 76 Fed. Reg. 73434, November 28, 2011.

episode of care for an individual. However, CMS indicates that this program will be developed during 2012.⁵⁴

To ease the implementation of the Physician VBP, CMS will implement an "initial performance period," tracking data from January 1, 2013 through December 31, 2013. This data will then be applied prospectively to future claims beginning in 2015, rather than retrospectively. CMS' justification for this approach is to avoid imposing burdens on physicians and beneficiaries.⁵⁵

At this writing, there are relatively few specifics regarding the Physician VBP program or its implementation. It is likely, though, that the Physician VBP will develop similarly to the Hospital VBP program. Thus, to understand the likely direction that the Physician VBP will take, one must examine the Hospital VBP and related programs, discussed further below.

2.5 The Physician Compare Website

The creation of the Physician Compare website⁵⁶ was mandated with the passage of PPACA.⁵⁷ The statute requires CMS to develop a website on which information derived from PQRS can be posted publicly. Although CMS opened this information for individuals or groups to view their own data in the 2011 Medicare Physician Fee

⁵⁴ 76 Fed. Reg. 77343, November 28, 2011. As of this writing, no such development had been made. *[Will have to revisit this when we get the galleys back.]*

⁵⁵ "Retroactive adjustments affect beneficiary cost sharing amounts, which would also need to be adjusted retrospectively. Requiring physicians to collect or refund small cost sharing amounts is operationally complex and confusing for beneficiaries. These same two issues arise if we were to use calendar year 2014 as the performance period for the 2015 payment adjustment year." 76 Fed. Reg. 73436, November 28, 2011.

⁵⁶ <http://www.medicare.gov/find-a-doctor/provider-search.aspx>.

⁵⁷ PPACA § 10331; 42 USCA § 1395w-5.

Schedule, PQRS and ERx data beyond merely the names of those physicians who successfully participated is not yet available to the public. CMS explained, "We expect, in the future, to publicly report information based on the Physician Quality Reporting System. It is conceivable that we could begin publicly reporting performance information based on the Physician Quality Reporting System starting with 2012 Physician Quality Reporting System performance results."⁵⁸ However, the statute requires that reports on physicians be publicly available no sooner than January 1, 2012, and no later than January 1, 2013. Therefore, absent a legislative change, public reporting will begin some time between those dates.

As of this writing, the Physician Compare website is relatively limited in scope, and only provides general information. The website allows visitors to search by ZIP code, as well as by thirty-nine different physician specialties, and by fifteen different types of non-physician practitioners.⁵⁹ However, the ultimate goal is to provide far more than a simple list of names. The public will be able to compare physicians and groups based on the data submitted under both PQRS and ERx. The statute requires that the information must include: (1) measures collected under PQRS; (2) assessment of patient health outcomes and functional status of patients; (3) assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use; (4) assessment of efficiency; (5) assessment of patient experience and patient, caregiver, and family engagement; (6) assessment of safety, effectiveness, and timeliness of care; and (7) other information determined by the Secretary of Health and

⁵⁸ 75 Fed. Reg. 73539, November 29, 2010.

⁵⁹ The full list of specialties and their descriptions can be found at <http://www.medicare.gov/find-a-doctor/staticpages/resources/glossary/Physician-Specialties.aspx>.

Human Services.⁶⁰ The data is required to be “statistically valid and reliable.” In addition, to the extent possible, the data must include more than merely Medicare information, although the other sources of such information are not specified.

When the system is finally online, CMS must also develop a process to allow physicians to review results before they are published, as well as a process “to ensure timely statistical performance feedback is provided to physicians concerning the data reported under any program subject to public reporting under this section.”⁶¹ CMS may also eventually include financial incentives for Medicare beneficiaries to select high-quality physicians, as determined by the Secretary of Health and Human Services and based on the various assessments described above. As with the Physician VBP, the Physician Compare website is still very much in development.

3.3 The Hospital Experience – A Glimpse Into the Future?

Physicians are not the only entities subject to quality measurement and reporting programs. In recent years, CMS began imposing reporting requirements on hospitals first. Whereas programs such as the Physician VBP and Physician Compare are relatively new, hospital versions of similar programs already exist. The experience of hospitals in addressing their own Inpatient Quality Reporting (IQR) and Hospital VBP programs, as well as how information on hospitals is made available to the public on the Hospital Compare website, therefore, provides insight into the direction CMS is likely to take with its physician quality reporting and measurement programs.

⁶⁰ 42 USCA § 1395w-5(a)(2).

⁶¹ 42 USCA § 1395w-5(b)(6). In addition, in response to a comment requesting that CMS provide a mechanism by which providers could report and correct data errors, CMS stated “Through regular data refreshes, CMS is working toward more accurate and up-to-date information on Physician Compare. We intend to conduct monthly refreshes and semi-annual updates as technically feasible. We look forward to engaging with providers and stakeholders to further address these concerns.”

3.1 The Hospital Inpatient Quality Reporting Program

The Hospital Inpatient Quality Reporting (IQR) system began as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program, with the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).⁶² The program revised the method by which hospitals update their standardized payment amount for inpatient hospital operating costs by providing a reduction of 0.4% to the update percentage increase (referred to as the "market basket update"), although the reduction would only apply to the then-current fiscal year for the hospital, rather than also applying in subsequent years. Initially, the program tracked whether hospitals submitted data on ten quality indicators. The program was later updated in the Deficit Reduction Act of 2005 to reduce payments by 2% for hospitals failing to submit quality data as required.⁶³ The program was modified again with the passage of the ACA, permitting CMS to require hospitals to report on still more measures, requiring CMS to make information on the measures submitted (but not the raw data itself) available to the public, and requiring CMS to take steps to provide risk adjustment as necessary to maintain incentives for hospitals to treat patients with severe illnesses or conditions with respect to quality measures for outcomes-of-care for payments beginning in fiscal year 2013; and, to align, as best as possible, hospital measures with physician quality measures.⁶⁴

⁶² 75 Fed. Reg. 50180, August 16, 2010. The RHQDAPU program's name was later changed to refer to the IQR.

⁶³ 75 Fed. Reg. 50181, August 16, 2010.

⁶⁴ 75 Fed. Reg. 50181, August 16, 2010. For a more detailed history of the RHQDAPU program, see the description in the 2011 Medicare Inpatient Prospective Payment System (IPPS).

Quality measures reported under the program include process of care measures, risk-adjusted outcomes measures, patient experience-of-care survey information, and structural measures. This includes information such as whether aspirin was delivered at arrival to heart attack patients; whether beta-blockers were prescribed at discharge for heart attack patients; vaccination status information; whether prophylactic antibiotics were given within one hour prior to surgical incision; as well as information on readmission and mortality for acute myocardial infarction, heart failure, and pneumonia thirty days after discharge.⁶⁵ Measures may be discontinued over time if there is a high, unvarying performance of the measure. For example, CMS previously retired a measure reporting whether an oxygenation assessment for pneumonia was performed, because of such unvarying performance.⁶⁶

Measures were initially based entirely on a hospital's submission of quality data derived from medical charts (also known as "chart-abstracted data"). In recent years, CMS has adopted measures that do not require chart-abstraction, such as structural measures and claims-based measures that can be calculated using other data sources.⁶⁷ The current IQR system tracks a variety of measures, including the measures discussed above, as well as measures such as: hip fracture mortality rates, participation in a systemic database for cardiac surgery, reports of air embolisms, influenza vaccination status, and adult smoking cessation counseling.⁶⁸

⁶⁵ For a list of measures used in the 2011 IPPS, see 75 Fed. Reg. 50183-50184, August 16, 2010.

⁶⁶ 75 Fed. Reg. 50185, August 16, 2010.

⁶⁷ CMS may ultimately expand this to include registries. See, 76 Fed. Reg. 51612, August 18, 2011. In addition, CMS plans to offer an EHR reporting option by 2015. 76 Fed. Reg. 51613, August 18, 2011.

⁶⁸ For a full list of the 2012 IQR measures, see 75 Fed. Reg. 50198-50199, August 16, 2010.

To participate, hospitals must register with QualityNet.org (Medicare's quality-reporting website), and submit a Notice of Participation Form.⁶⁹ Hospitals must then submit the measures in accordance with CMS's requirements.⁷⁰ However, a hospital may be granted a waiver or extension of one or more data submission deadlines in the event of "extraordinary circumstances beyond the control of the hospital."⁷¹ Hospitals may be required to submit patient charts for validation of the measures they report.⁷²

Similar to PQRS, a hospital may request a reconsideration of a determination that it has failed to properly report the IQR measures. Hospitals have thirty days from the date identified on their Hospital Inpatient Quality Reporting Program Annual Payment Update Notification Letter to request such a reconsideration.⁷³ However, unlike PQRS, if a hospital is dissatisfied with the results of the reconsideration, it may file an appeal with the Provider Reimbursement Review Board.⁷⁴

⁶⁹ For the full requirements to participate, see 42 CFR § 412.140(a).

⁷⁰ The regulations state that specific requirements for submission of a request for an extension or waiver are available on QualityNet.org. For further discussion of the current and planned future requirements for data submission, see also, 76 Fed. Reg. 51640-51645, August 18, 2011.

⁷¹ 42 CFR § 412.140(c)(2). Also referred to as "disaster waivers," which CMS will grant in cases such as a natural disaster like a hurricane. CMS also retains the authority to grant such a waiver without a request from a hospital. 76 Fed. Reg. 51652, August 18, 2011.

⁷² 42 CFR § 412.140(d). Patient charts must be submitted within 30 days of the date of a written request from CMS.

⁷³ 42 CFR § 412.140(e)(1). For a complete list of what a reconsideration request must contain, see 42 CFR § 412.140(e)(2). However, reconsideration requests may be granted only in specific circumstances, such as a request for reconsideration for CDAC (the reviewing entity) contractor-abstracted data elements classified as mismatches affecting validation scores; when the hospital's record copies submitted during validation have been classified as "invalid record selections"; or, for medical records not submitted within the thirty calendar day deadline. "Invalid record selections" are described by CMS as "medical records submitted by hospitals during the quarterly validation process that do not match the patient's episode of care information as determined by the CDAC contractor (in other words, the contractor determines that the hospital returned a medical record that is different from that which was requested)." 76 Fed. Reg. 51615, August 18, 2011.

⁷⁴ 42 CFR § 412.140(e)(3).

3.2 The Hospital Value Based Purchasing Program and Hospital Compare

The Hospital VBP program was implemented by PPACA, with final regulations published in 2011.⁷⁵ The program draws its data from measures reported by hospitals under the Hospital IQR program. In explaining its overall view of the Hospital VBP program, CMS has stated that it sees the program “as the next step in promoting higher quality care for Medicare beneficiaries and transforming Medicare into an active purchaser of quality health care for its beneficiaries.”⁷⁶ Moreover, CMS has stated that, to the extent possible, it wants to align measures across the Medicare and Medicaid public reporting and payment systems.

In general, hospitals participate in the Hospital VBP program by submitting data which is compared to previously submitted data on performance measures. CMS has established “baseline” reporting periods for different measures. Participating hospitals will then report for a “performance period” for each measure. The improvement between the baseline and performance periods is then compared to an established benchmark for the specific measure. In general the benchmark performance standard is defined as “performance at the mean of the top decile of hospital performance during the baseline period.”⁷⁷ The hospital’s total performance across multiple measures is then calculated and evaluated.⁷⁸ If the hospital fails to show improvement, all of its diagnosis related group (DRG) payments are reduced. If the hospital shows improvement, it receives an

⁷⁵ PPACA § 3001(a). 76 Fed. Reg. 26490, May 6, 2011.

⁷⁶ 76 Fed. Reg. 26490-26491, May 6, 2011.

⁷⁷ 76 Fed. Reg. 26496, May 6, 2011.

⁷⁸ For a detailed discussion of the mechanism used to calculate total performance, see, 76 Fed. Reg. 26513-26527, May 6, 2011.

incentive payment. However, the opportunity to improve on a given measure will not last indefinitely. Over time, measures may be retired when it becomes clear that hospitals have improved sufficiently in those areas.⁷⁹

The Hospital VBP program still has issues regarding program overlap with the IQR system. Both programs exist alongside each other and will continue to do so for the foreseeable future. However, a hospital which fails to satisfactorily report under IQR cannot participate in Hospital VBP.⁸⁰ The hospital in this case will receive a reduction to its applicable percentage increase for that fiscal year under the IQR, but will not otherwise be affected by the Hospital VBP. If a hospital does not meet its requirements to participate in IQR during a fiscal year, it will not be subject to the DRG reduction under the Hospital VBP program, nor eligible to receive an incentive payment under Hospital VBP for that fiscal year.⁸¹ The results of a hospital's participation in Hospital VBP will also be posted on CMS's Hospital Compare website.⁸²

Hospital Compare permits consumers to search hospitals by zipcode, as well as medical condition⁸³, and surgical procedure.⁸⁴ The Secretary of Health and Human

⁷⁹ 76 Fed. Reg. 26499, May 6, 2011.

⁸⁰ 76 Fed. Reg. 26493, May 6, 2011.

⁸¹ 76 Fed. Reg. 26494, May 6, 2011. However, CMS recognizes the potential regulatory "dodge" this offers hospitals. "We are concerned about the possibility of hospitals deciding to opt out of the Hospital VBP program by choosing not to submit data under the Hospital IQR program, thereby avoiding both the base operating DRG payment reduction and the possibility to receive a value-based incentive payment, although we recognize that these hospitals would still be subject to the Hospital IQR program reduction to their applicable percentage increase for the fiscal year. We intend to track hospital participation in the Hospital IQR program and welcome public input on this issue." 76 Fed. Reg. 26528, May 6, 2011.

⁸² Located at <http://www.hospitalcompare.hhs.gov/hospital-search.aspx>.

⁸³ Including heart attacks, heart failure, chronic lung disease, pneumonia, diabetes in adults, and chest pain.

⁸⁴ Including heart and blood vessels, abdominal, neck/back/arms/legs, bladder/kidney/prostate, and female reproductive, each of which is broken down into specific services for that part of the anatomy.

Services is required by law to develop procedures to gradually make public the quality data gathered from the IQR and to permit hospitals to review the data before it is publicized.⁸⁵ There is, however, apparently no mechanism for a hospital to challenge the information posted on the website, to have it removed or modified.

The implication of this integrated hospital quality reporting effort of joining quality reporting systems (the IQR system), with incentive payments for improved performance, as well as a public reporting component all provide a potential model for how CMS physician-oriented programs will ultimately develop. Whereas, in the past, the quality reporting programs merely incentivized the reporting of data, the Hospital VBP program and eventually the Physician VBP program incentivizes actual improvement on metrics. Moreover, the benchmarks and baseline information for the Hospital VBP program are derived from previously reported data under the IQR, just as the Physician VBP program derives its information from PQRS. The use of Hospital Compare also illustrates how CMS is likely to eventually use the similar Physician Compare website, which raises concerns for physicians facing this new quality reporting and measurement landscape.

4 Pitfalls and Complications

The Federal government's quality tracking systems and programs will necessarily impact those entities that report. While those that successfully report may receive financial benefits, failure to properly report may result in financial penalties. As discussed above, participation in certain programs may preclude participation in others. However, current quality reporting programs are relatively new and have changed rapidly

⁸⁵ Deficit Reduction Act of 2005, section 5001.

in recent years, and thus many participating physicians and practices may have yet to encounter the problems that may await them in and around these systems. The remainder of this chapter explores the potential and known problems that arise from physician participation in the federal quality reporting and measurement programs.

4.1 Failures, Errors, and Overpayments

The most obvious consequence of failing to report at all or failing to properly report to one of the Federal quality reporting programs is the financial penalty. Under PQRS and the ERx program, if the EP or group does not meet the requirements for reporting, or does not fit an applicable exemption, the abovementioned "payment adjustment" will be applied. The "payment adjustment," when it is eventually applied, is a prospective adjustment to concurrent claims, rather than a retrospective adjustment applied to previously submitted claims.

However, unlike a scenario where a payment adjustment is applied to penalize the EP's failure to successfully (but still accurately) report, there exists additional risk in the form of potential overpayments where information is reported incorrectly, but only discovered to have been incorrect after the fact. Under the Fraud Enforcement Recovery Act of 2009 (FERA) as modified by PPACA, the Federal False Claims Act (FCA) was changed to apply false claims liability to the retention of overpayments for longer than sixty days after they have been (or should have been) identified, without regard to the actual intent of the party retaining the overpayment.⁸⁶ Violations of the FCA are subject to up to \$11,000 per false claim, plus triple the government's damages.⁸⁷

⁸⁶ PPACA § 6402.

⁸⁷ 31 USCA § 3729.

Although there has yet to be any enforcement along these lines as applied to the federal quality reporting systems, one possible scenario could be where an EP submits data as part of PQRS. The EP improperly reports measures data, but receives the incentive payment anyway due to an error on CMS' part. Under this scenario, sixty days after the EP knew or should have known that it was not entitled to the incentive payment, it will convert to an overpayment and potentially subject the EP to false claims liability.

Another variation on this scenario could occur where a group practice participating in the PQRS program reports on claims for services, where the services themselves were improperly billed (but where the QDC would have been properly reported, had the underlying service been legitimate). This fact is later discovered by the local Medicare contractor, which demands a repayment for the underlying claims. Because the PQRS incentive payment (as with the ERx incentive payment) is based on a percentage of the EP's Medicare Part-B reimbursement, if the EP has received its incentive payment before the local contractor discovers the improperly billed claims, the EP might have to repay the difference between its initial incentive payment and the ultimate final amount based on the adjusted claims. To put this example into concrete numbers, if the EP received 0.5% of its Part-B reimbursement, and that amount totaled \$10,000 but was based on a total reimbursement of \$2 million, when that \$2 million figure is reduced to \$1.5 million due to improperly paid claims, the EP will have to repay an additional \$2,500 of its incentive payment to account for the difference between the incentive it received which was itself based on improper claims, and the incentive to which it was actually entitled following claims adjustment. Moreover, if it is discovered that the EP was not entitled to bill for the claims at all, and therefore its total number of

submitted claims was insufficient to meet the reporting requirements in the first place, the EP will have to repay the *total* amount of the incentive payment.

Unfortunately, given the timing of the incentive payments themselves, such scenarios remain a possibility for physicians and groups participating in these programs. Because these systems lack a feedback mechanism concurrent with claims submission, and only provide periodic feedback on whether the EP or group successfully participated after the final determination has been made (or in some circumstances through interim reports), participating physicians and groups may not even be aware that they have a problem at all. Therefore, physicians and group practices might end up having to, in effect, make two repayments based on one improper claim. These problems will only be compounded as more systems are aligned along the same quality measures.

Of far greater concern, however, is the fact that physicians and groups which have made voluntary repayments while participating in the Federal quality reporting programs may be sitting on an overpayment timebomb without even realizing it. Physicians and groups which have made repayments for improperly billed claims and which received incentive payments prior to making such repayments should closely examine their records to determine whether they must also make a repayment based on the adjusted percentage of Part-B reimbursement, or whether they must repay the total amount of the incentive payment. Failing to do so could cause the retained difference in incentive payments to be seen as an overpayment, thereby subjecting the physician or group to false claims liability.

4.2 Appeals and Exemptions

Unlike other elements of the federal healthcare system, the quality reporting systems usually lack any kind of formalized appeals process to challenge determinations of whether a provider has successfully participated in a reporting program, or the amount of the incentive payment or payment adjustment applied to the provider. They also may lack an avenue by which providers can challenge the public reporting of their participation status. Although some systems have built-in exemptions to participation, not every program or system has implemented such exemptions.

At present, none of the federal reporting programs include processes allowing for judicial or administrative review of any determinations; the PQRS system explicitly bars such review.⁸⁸ The public reporting programs such as Hospital Compare also do not include a process by which formal appeals or challenges to posted information may be made. When it begins to publicly report quality information on physicians, Physician Compare will also lack anything beyond an informal appeals process, similar to that of Hospital Compare. Finally, the Hospital VBP program has relatively restricted avenues of appeals, and the Physician VBP program does not yet even address such a concept.

The lack of a formal appeals process when challenging the amount of an incentive payment is perhaps frustrating, but at least carries no punitive effect. While an EP in one of the programs might lose the opportunity to receive the full amount it had hoped for, receiving a smaller payment than hoped for is not necessarily a burden (although it is certainly an inconvenience). Of greater concern, however, is the lack of any ability to formally challenge a payment adjustment, due to CMS's determination that the EP did

⁸⁸ 42 CFR § 414.90(h).

not successfully participate. Given that such a determination will result in a reduction of Medicare Part-B reimbursement, the effect of such a decision is clearly punitive.

When the public reporting of successful (or unsuccessful) participation begins, the inability to challenge one's status as a successful EP will grow in importance, as will the inability to challenge what is displayed on the Physician Compare website (assuming Physician Compare eventually follows the model used by Hospital Compare). This information is likely to inform consumer decisions in the health care marketplace. If CMS decides to incentivize Medicare beneficiaries' selection of high-performing providers, the pressure to ensure that one's data is accurately reported will be even greater, lest beneficiaries seek services elsewhere.

4.3 System Overlap

The various Federal quality reporting systems do not always align perfectly. In a recent letter from the American Medical Association (AMA) to CMS regarding PQRS, the AMA stated,

“It is critical that CMS acknowledge the lack of alignment in reporting methods between the PQRS and the EHR Incentive program (meaningful use, or MU). For example, the MU program requires a quality measure to be calculated with in the certified EHR technology, whereas for PQRS EHR reporting, the EHR vendor must be a -designated PQRS EHR Vendor,ö and raw data is sent to a data warehouse with the measure being calculated outside the physician's EHR system.”⁸⁹

While CMS has explained its reasons behind keeping the certification requirements for EHR software distinct under each program, and while it has offered to provide a list of dually certified EHR software, this disconnect is merely the tip of the iceberg.

⁸⁹ AMA PQRS Town Hall Letter, p. 6, February 25, 2011.

PQRS and Meaningful Use both employ similar (in some cases identical) reporting data. In some respects, this can be a benefit to participating physicians, but it can also mean that an error made in one system can carry over into another. In other words, a single error can be compounded across multiple systems, jeopardizing successful participation in each. Given that CMS has indicated its intention to harmonize reporting mechanisms across multiple reporting systems, the implications of this problem are only likely to grow.

In addition, as discussed above, incentive payments under ERx and Meaningful Use are mutually exclusive. Physicians and groups may choose to opt out for the 2012 reporting period only to avoid the requirements (and thus the payment adjustments) under ERx by participating in Meaningful Use that year. However, given the timing of reports under ERx, a physician or group may not have sufficient time to meet the Meaningful Use requirements if it is unable to comply with the ERx requirements. While the regulations do specifically prohibit payments under both systems, there is also no clear mechanism by which an EP or group which successfully participates in ERx and a physician who is a successful meaningful user under the Meaningful Use program may designate which incentive they wish to receive. This would seem to preclude hedging one's bets by simultaneously participating in both systems.

As discussed above, the group practice reporting option under ERx presents additional concerns with respect to overlapping programs, especially with respect to physicians who reassign their right to payment to a group which opts to participate in ERx. By virtue of the physician's association with a group practice that opts to report as a group *for ERx* or even if work for the group represents a small portion of the physician's

practice revenues ó he or she may find him or herself barred *from receiving Meaningful Use incentive payments* as an individual.

This is particularly problematic for physicians who operate their own practices, but also provide services to other groups to which the physicians reassign their right to payment. The decision by those other groups ó a matter in which the reassigning physician may have no say ó may present a bar to the reassigning physician advancing his or her own practice by offsetting the expense of adopting an EHR with Meaningful Use incentive payments. Combined with the fact that the ERx program does not currently include a mechanism by which such a physician may ðopt outð of being ðcountedð under a groupø ERx reporting,⁹⁰ physicians who reassign their rights to payment, and who intend to participate in the Meaningful Use program through their own practices, will need to carefully review their relationships with groups to which they reassign when those groups are reporting using the group-reporting option under ERx.

4.4 Establishing Standards of Care and Other Effects of Public Reporting

The development of Federal quality reporting systems likely also heralds the development of new industry-wide standards of care for medical malpractice purposes. At present, given the newness of these programs, there is a relative dearth of case law directly on point. Measurements reported under PQRS, for example, have yet to be used as establishing any kind of ðstandard of care.ð As the government begins to establish benchmarks for quality, those physicians and groups who fail to meet the benchmarks and who injure patients in ways covered by the benchmarks will likely find themselves subject to medical malpractice lawsuits based on a failure to meet the standard of care.

⁹⁰ Interestingly, Meaningful Use does permit a participating physician who achieves ðmeaningful userð status to designate the tax identification number to which payment should be made. 42 CFR § 495.10.

Especially given the degree of data that may ultimately be publicly available on such issues, it may become simple to compare a given physician to the national benchmark established by CMS and to use that physician's failure to meet the benchmark as evidence of a failure to meet the standard of care.

Similar approaches have been applied to state quality reporting mechanisms, however. For example, The Commonwealth of Pennsylvania requires the reporting of certain data by hospitals under the Pennsylvania Health Care Cost Containment Act.⁹¹ In Angelico v. Lehigh Valley Hospital, Inc.,⁹² the District Court for the Eastern District of Pennsylvania addressed a lawsuit in which a physician who had been denied surgical privileges at regional hospitals sued the hospitals and a health care association, alleging a group boycott. Although the primary focus of the case was unrelated to quality reporting, the judge indicated that a plaintiff's antitrust expert could use mortality and admission severity group data reported to the Pennsylvania Health Care Cost Containment Council (HC4) to offer an opinion on the quality of surgical care available in the Lehigh Valley area. While the case did not explicitly involve the establishment of a standard of care for malpractice purposes, it does demonstrate how public reporting of quality data mandated by law could establish a standard of care within a community.

In TH Services Group, Inc. v. Independence Blue Cross, et al.,⁹³ a lawsuit was filed by a New Jersey-based health care auditing firm against Blue Cross third-party payors. The case related to a claim that the Blue Cross entities had improperly estimated

⁹¹ 35 P.S. §§ 449.1 to 449.19. See 35 P.S. § 449.7 for specific information on the type of data published under PCH4.

⁹² Angelico v. Lehigh Valley Hospital, Inc., 984 F. Supp. 308, at 313 (E.D. Pa., 1997).

⁹³ TH Services Group, Inc. v. Independence Blue Cross, et al., 2001 WL 115041 (E.D. Pa. 2001).

discounts given by hospitals. After requesting certain data from the Blue Cross entities, the auditing firm turned to the data available from HC4. Again, while not directly tied to establishing standards of care, the case helps illustrate the ways in which publicly reported data may ultimately be used by third parties.

The implications of these cases are that public data will not simply be used by consumers to determine where they obtain their health care services; such data may also serve as the basis for a standard of care, or may even be used for unrelated purposes.⁹⁴ Towards this end, it will be essential for physicians and groups to ensure that their information is correctly reported and displayed on the Physician Compare website when such information is finally public. The information will be a matter of public record, available to any plaintiff's attorney with a web browser, so the accuracy of a physician or group's information will be critical. Accurately reported information also need not only be used as a sword by plaintiff's counsel; it may also be used by defense counsel, if the data establishes adherence to or performance above established quality benchmarks.

The potential impact of this type of data on physicians and physician groups only serves to further highlight the problems with a lack of any formal appeals process to challenge the information that is publicly posted. While it may prove that CMS is willing to correct errors if and when they arise, there is no established mechanism by which CMS

⁹⁴ For an excellent discussion of the implications of quality data, including the potential development of national quality standards, see, Gosfield and Reinertsen, "The 100,000 Lives Campaign: Crystallizing Standards Of Care For Hospitals," *Health Affairs*, November/December, 2005, pp. 1560-1570.

is required to do so. It will therefore be incumbent upon physicians and groups to monitor their own information carefully, to ensure its accuracy.

5 Conclusion

The reporting and measurement of quality data in the health care industry continues its inexorable development. With the passage of PPACA, Congress set forth requirements that CMS enhance its existing programs, and transition towards a value-oriented payment model, rather than a volume-oriented model. That CMS must also develop publicly available websites providing information on the quality of physicians' services only raises the stakes for physicians and group practices, especially in difficult economic times.

What were previously simply "pay for reporting" systems are shifting to a "pay for performance" model, which will punish failure to report and poor quality services alike. Moreover, data that was previously reported and simply collected by the government is likely to form the basis for future benchmarks for such a "pay for performance" system. The Physician VBP and the programs associated with it — chief among them, PQRS — is the culmination of this trend. It will therefore be essential for physicians and groups to understand the interaction between the data they report and how that data may be publicized and/or further used. Physicians must also understand the implications of failure to properly report.

The ground, therefore, is shifting under physicians' feet, and at a rapid pace. Year-to-year changes in these programs only increase the difficulty in understanding a physician's obligations under these programs, as subtle tweaks to reporting systems and potential repercussions in other related — and often overlapping — reporting systems only

further muddy the water. As physicians seek to untangle this skein, a clear understanding of the interaction between these various programs will be essential. Likewise, physician counsel will need to keep an eye towards the horizon, so as to anticipate impending changes. Because several of these programs carry implications for physicians' bottom lines in the future (such as reporting periods a year or more in advance of the applicable program year), it is critical to understand the current and ever-shifting landscape posed by these programs.