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TO QUALITY AND BEYOND!: THE PRESENT AND FUTURE OF MEDICARE'S PHYSICIAN QUALITY REPORTING PROGRAMS

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To Quality And Beyond!

The Present and Future of Medicare's Physician Quality Reporting Programs

1. Introduction

As Baby Boomers begin to age into Medicare eligibility, the Medicare program itself is faced with a significant demographic challenge. Current projections estimate that the Medicare Hospital Insurance Trust Fund (responsible for paying for Medicare Part-A) will be depleted by 2030, and will require either a payroll tax increase from 2.9% to 3.3%, or an immediate, permanent reduction in spending by 10%.[1] Without considerable reform to the Medicare fee-for-service (FFS) payment system, there would simply not be enough money to pay for the program without either tax increases or benefit cuts. There had been previous attempts to mitigate these challenges, such as the Sustainable Growth Rate (SGR) in 1997[2], but the SGR proved to be a political nonstarter, and reductions in payments under the Medicare Physician Fee Schedule were postponed for 18 years. The SGR ultimately amounted to little more than accounting chicanery. At the time of its elimination, the SGR would have imposed a 21% cut on FFS payments for physicians and certain non-physician practitioners.[3] Faced with this untenable position, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).[4]

However, MACRAôs elimination of the SGR resulted in a budgetary gap. The SGR had

[1] MedPAC June 2015 Report to Congress, Ch.2, p. 53. http://www.medpac.gov/documents/reports/chapter-2-the-next-generation-of-medicare-beneficiaries-%28june-2015-report%29.pdf?sfvrsn=0.

[2] As part of the Balanced Budget Act of 1997, P.L. 105-33.

[3] Because many of these programs apply both to physicians and to certain non-physician practitioners, this article refers to ñprofessionalsò in the interests of brevity.

[4] P.L. 114-10.

allowed Congress to keep Medicare ñbudget neutral,ò even as it ñkicked the can down the road.ò To fill this gap, Congress created new programs designed to control Medicare costs, including the Merit-Based Inceptive Payment System (MIPS). Programs like MIPS represent a shift in Medicareôs payment methodologies. Under FFS, healthcare services are treated akin to widgets: the more you make, the more you are paid.[5] MIPS and its ilk, however, shift payment towards a focus on both value and quality.

This shift, however, did not begin in 2015. To the contrary, Medicare has been developing and deploying similar systems ï including those on which MIPS will rely ï for several years as part of an overall, system-wide shift towards paying for value and quality, and an effort to increase transparency. Systems such as the Physician Quality Reporting System (ñPQRSò), the Electronic Health Records Incentive program (also known as ñMeaningful Useò or ñMUò), the Value-based Payment Modifier (VPM), and Physician Compare all pre-date the introduction of MIPS. The Health Law Handbook last examined these programs in its 2012 edition.[6] At the time of publication, the VPM was still very much in its infancy, and did not have implementing regulations, although that has changed in the interim. So too have the PQRS, MU, and Physician Compare programs.

This article examines the current systems in place, how they have changed, and how they will function in the foreseeable future. It also explores what we know about MIPS and how it will operate, with an eye towards the programs which form the backbone for MIPS, including the type of information that must be reported. This article will further address how these programs

[5] Of course, Congress and CMS have also attempted to curtail the ñoverproductionò of such ñwidgetsò through disincentives such as the Antikickback Statute and the Stark law.

[6] Shay, Daniel F., PQRS and its Penumbra, HEALTH LAW HANDBOOK, 2012 ed., pp. 87-119.

relate to each other, and the potential pitfalls underlying each of these systems -- especially with regards to possible false claims liability.

2. The Current Landscape

At the present time, our understanding of MIPS is not even as complete as was our understanding of the VPM in 2012. There have been, to date, no regulations published for the program, and it is unlikely any will be published before 2017. However, MIPS will initially be based on information collected from several existing programs during the years prior to the ñgo-liveò date for MIPS. Understanding how these programs function at present can shed light on what physicians can expect in the coming years. Accordingly, this section discusses the current landscape in Medicareôs quality-oriented programs, specifically: PQRS, MU, the VPM, and Physician Compare.

2.1 The Physician Quality Reporting System

The Physician Quality Reporting System (ñPQRSò) actually began as an ñinitiativeò in 2007, and not as a true program. At its inception, the initiative incentivized the reporting of data by offering ñeligible professionalsò (ñEPsò ï which includes physicians and non-physician practitioners who submit claims under Medicare Part B ï as well as groups of EPs) a payment bonus for doing so.[7] The program was never intended to measure the quality of performance for any of the reported activities; it was only meant to track the reporting data in response to defined quality measures. In essence, this is ñpay for reporting,ò rather than ñpay for performance.ò[8] The initiative was transitioned to a full-fledged ñsystemò with the 2010 passage of the Patient

[7] Originally, this amount was a 1.5% increase in the EPôs Medicare Physician Fee Schedule payments for 2007 and 2008, which grew to 2.0% for 2009 and 2010, and thereafter reduced to 1.0% in 2011, and finally to 0.5% in 2012 through 2014. 42 CFR § 414.90(c)(3).

[8] Medicare Physician Fee Schedule, 76 Fed. Reg. 73426, November 28, 2011.

Protection and Affordable Care Act of 2010 (PPACA).[9]

Over time, CMS gradually reduced the payment incentives, and transitioned to a system which, through the imposition of so-called ñpayment adjustments,ò penalized failure to report; the carrot was gradually swapped out for the stick. By 2015, failure to properly report (or opt out of Medicare altogether) would result in a -2.0% payment adjustment for all Medicare services, including even those services not otherwise affected by the reported measures.[10] The system operates on what can best be characterized as a two-year ñlag.ò Current payment adjustments are based on data reported two years ago, and data reported today will form the basis for payment adjustments two years hence.

This shift to a two-year lag approach for payment adjustments began in 2013. Thus, data reported in 2013 formed the basis for 2015 payment adjustments; data reported in 2014 forms the basis for payment adjustments in 2016; data reported in 2015 forms the basis for payment adjustments in 2017, and so on. The two-year lag approach arose for two related reasons. First, CMS did not want to engage in retroactive payment adjustments. When PQRS was purely an incentive program, CMS based payment incentives on data reported for claims submitted during the previous year; in other words, payment received in 2011 was based on data reported in 2010. Imposing payment adjustments the same way, however, would put CMS in the position of having to constantly ñchase moneyò and recoup payments already made to professionals. Instead, CMS opted to apply payment adjustments to claims submitted concurrently; therefore, data *reported on claims from 2013* would result in a payment adjustment for claims that were

[9] PPACA, section 10327; 42 CFR sec. 414.90. For a more detailed history of PQRS, see also, Shay, Daniel F., PQRS and its Penumbra, HEALTH LAW HANDBOOK, 2012 ed., pp. 87-119.

[10] 42 CFR § 414.90(e).

paid in 2015.

CMS explained that it had to adopt a two-year lag (rather than the then-more-common one-year delay) because it was,

> ñnot 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 claimsé If we do not reduce the [Physician Fee Schedule] 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 adjustment applies, or alternatively, hold claims until such a determination is made.ò[11]

Although participation in PQRS is not mandatory, failure to participate will result in the imposition of payment adjustments.[12]

2.2 PQRS Reporting Methods and Types of Data Reported

Several options are available to EPs in terms of how they may report PQRS data.[13] These include several options for reporting as individuals, as well as methods available to groups of EPs. Individual practitioners can report by submitting claims for services with quality data codes (QDCs) on the claims themselves.[14] EPs can also report using registries, which act as intermediaries for EPs.[15] Here, the EP sends data to the registry, and the registry reports the

[11] 76 Fed. Reg. 73391-73392, November 28, 2011.

[12] Failure to report will also implicate MIPS, but this is addressed more fully below at 4.2.

[13] For more information regarding how information is submitted to CMS, see Shay, Daniel F., PQRS and its Penumbra, HEALTH LAW HANDBOOK, 2012 ed., pp. 87-119.

[14] To satisfactorily report in 2016 and avoid a payment adjustment in 2018, individual EPs reporting via claims must report on at least 9 measures, covering at least 3 National Quality Strategy (NQS) domains, and must report each measure for at least 50% of the EPôs Medicare Part-B fee for service patients seen during the reporting period. This must include at least 1 cross-cutting measurement. Reporting may be done for all twelve months of 2016. See, Table 27, 80 Fed. Reg. 71148, November 16, 2015. Tables 27 and 28 (80 Fed. Reg. 71148-71150, November 16, 2015) detail the reporting requirements for both individual EPs and group practices across the full range of reporting methods.

[15] For a full list of registries certified for 2015, see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015QualifiedRegistries.pdf.

QDCs to CMS. In 2013, CMS added the option for EPs to report using electronic health records (EHR) software.[16] The Group Practice Reporting Option (GPRO) also allows groups of EPs to report together through a web-based portal maintained by CMS.[17]

In 2014, CMS also added the option to report using Qualified Clinical Data Registries (QCDRs), which, similarities in name notwithstanding, are not the same as the registries described above. CMS describes QCDRs as a CMS-approved entity (inclusing registries, certification boards, collaboratives, etc.) that collect medical and/or clinical data for patient- and disease-tracking purposes; one of the key differences between a qualified registry and a QCDR is that QCDRs may submit information from five categories[18] outside of the measures normally tracked by PQRS. Instead, QCDRs may track up to 30 non-PQRS measures from several different categories. QCDRs may self-nominate, after which they must meet certain requirements and be approved by CMS.[19] These QCDRs then collect information from EPs, and submit the data to CMS. In addition, the information collected and submitted applies to all payors, not merely Medicare.[20]

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[16] 42 CFR 414.90.

[17] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/gpro_web_interface.html.

[18] The categories for QCDR submission include the following: Current PQRS measures; National Quality Forum-endorsed measures; Clinician & Group Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures; Measures used by specialty boards or specialty societies; and, measures used in regional quality collaborations. 2015 Physician Quality Reporting System (PQRS): Qualified Clinical Data Registry (QCDR) Participation Made Simple, January, 2015, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015PQRS_QCDR_MadeSimple.pdf.

[19] Further details on the self-nomination process, including links to criteria and a self-nomination toolkit, can be found at CMSô web page for QCDRs, located at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/qualified-clinical-data-registry-reporting.html.

[20] CMS explicitly states ñThe data submitted to CMS via a QCDR covers quality measures across multiple payers and is not limited to Medicare beneficiaries.ò 2015 Physician Quality Reporting System (PQRS): Qualified Clinical Data Registry (QCDR) Participation Made Simple, January, 2015, p. 2.

The number of PQRS measures have grown over time.[21] For reporting in 2015, there were a total of 255 measures.[22] For reporting in 2016, that number ***rose*** to approximately 300 total measures.[23] These measures track a broad range of information.[24] For example, Measure #154 tracks the percentage of patients aged 65 and older who are given a risk assessment for falls in the previous twelve months; Measure #160 tracks the percentage of patients diagnosed as HIV/AIDS positive who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis; and Measure #238 tracks the percengage of patients aged 66 and older who were ordered high-risk medications, ranging from first-generation antihistamines, to certain pain medications, to certain types of estrogen medications.[25] Each of these three measures can be reported by any of the different methods, such as by claims-based reporting, reporting via registry, and reporting via EHR. Measure #154 may be reported using claims-based reporting, reporting via registry, and reporting via EHR.[26] Measure #160 can be reported via EHR, and via measure group reporting.[27] Measure #238 can be reported via EHR, measure group reporting, and registry. All

[21] Although, CMS has, in some years, reduced the total number of measures, as between 2014 and 2015 where the number wentfrom 284 to 255, the total number has generally risen over time. See, ñPhysician Quality Reporting System: Whatôs New for 2014,ò at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/downloads/2014pqrs_whatsnew_f01-09-2014.pdf.

[22] http://www.mdinteractive.com/2015-PQRS.

[23] ***CITE. Try to find a final tally of the total# of measures. No luck yet.***

[24] For a full list of measures for 2016 reporting, see https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html. This page contains a number of helpful documents including both the full list of measures, and instructions for reporting the measures.

[25] See, ñ2016 Physician Quality Reporting System (PQRS) Measures Groups Specifications Manual,ò pp. , and 447, respectively, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html.

[26] 80 Fed. Reg. 71153, November 16, 2015. See also, the full list of measure codes for 2016, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html.

[27] See the full list of measure codes at, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html.

three measures may be reported via the GPRO web interface, as well.[28]

Reported data also includes information from consumer surveys, such as the Consumer Assesment of Healthcare Providers & Systems (CAHPS) survey. This data surveys consumers on their experiences, rather than on their satisfaction.[29] Currently, CAHPS data is collected by vendors certified by CMS, and is meant to supplement PQRS reporting for group practices only. Today, groups of twenty-five or more EPs must report CAHPS information. However, if CMSô past behavior is any guide, the reporting requirement will likely be applied to groups of two or more, and eventually to solo EPs in future years.

Interestingly, CMS is also conducting PQRS audits, announcing, ñWe are in the process of auditing PQRS participants, including vendors who submit quality measures data. We believe it is essential for vendors to cooperate with this audit process.ò[30] Under this new auditing program, vendors are required to provide contact information for those EPs on which the vendor reports. The term ñvendorò includes EHR vendors, QCDRs, qualified registries, data submission

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[28] 80 Fed. Reg. 71228, 71233, November 16, 2015.

[29] CMS notes the distinction on its website discussing CAHPS, under the section heading ñExperience is not the same as Satisfaction.ò The web page reads, ñPatient experience surveys sometimes are mistaken for customer satisfaction surveys. Patient experience surveys focus on how patients experienced or perceived key aspects of their care, not how satisfied they were with their care. Patient experience surveys focus on asking patients whether or how often they experienced critical aspects of health care, including communication with their doctors, understanding their medication instructions, and the coordination of their healthcare needs. They do not focus on amenities.ò https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/index.html?redirect=/CAHPS/.

[30] 80 Fed. Reg. 71140, November 16, 2015. CMS has explained that the audit process, known as Primary Source Verification (PSV), is designed to verify the clinical data and measures submitted by EPs, to improve data quality for both PQRS and the E-Prescribing program (eRx). CMS has published an information paper on PSV, as well as an FAQ list, at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PSV_Information_Paper_Awareness_Final-03232015.pdf, and https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PSV_FAQ_Revised.pdf, respectively.

vendors, etc.[31] All submitted data must be retained for at least seven years.[32]

2.3 Meaningful Use

[This section may need to be updated, depending on what CMS does in response to the additional 60-day comment window in response to the publication of the Stage 3 rules. The window closes December 16. No idea when CMS will publish its response to the comment period. If it's after we get the galleys back, I'll include a note here about how – at the time of writing – we were waiting on additional comment.]

The CMS Electronic Health Records Incentive Payment system, also known as ñMeaningful Useò (or ñMUò) is a program designed to spur the adoption of EHR software within the health care industry, especially by eligible practitioners (EPs).[33] It was created as part of the American Recovery and Reinvestment Act of 2009, specifically the Health Information Technology for Economic and Clinical Health Act (HITECH).[34] Regulations implementing the MU program were published in 2010.[35] Initially, the program was incentive-based, and issued payments to those EPs who successfully adopted and used certified EHR software.[36] Since its inception, the program has transitioned from one that exclusively provided incentive payment

[31] 80 Fed. Reg. 71140, November 16, 2015.

[32] 80 Fed. Reg. 71140, November 16, 2015.

[33] Unfortunately, CMSô terminology for individuals who may participate in programs such as PQRS and MU tend to overlap, although they differ slightly from program to program. For example, the MU definition of an ñEPò includes only allopaths and osteopaths, chiropractors, dentists, optometrists, and podiatrists. 42 CFR §§ 405.4; 405.100. By contrast the PQRS definition is far more expansive, and includes physicians, physical therapists, occupational therapists, audiologists, and practitioners as defined by § 1842(b)(18)(C) (which itself includes physician assistants, nurse practitioners, registered dietitians, etc.). 42 CFR § 414.90(b).

[34] P.L. 111-5, Title XIII, section 13001, et seq.

[35] 75 Fed. Reg. 44314-44585, July 28, 2010.

[36] A list of certified software can be found at https://www.healthit.gov/policy-researchers-implementers/certified-health-it-product-list-chpl. Note that, for 2015, software must be certified to the 2014 standards. For 2016-2017, software may be certified to either 2014 or 2015 standards. 42 CFR § 495.4.

ñcarrotsò to one which will eventually only apply the ñstickò of payment adjustments for failure to adopt or properly use EHR software.

To participate, EPs must attest to their meaningful use of EHR software in accordance with the then-applicable requirements. These requirements differ, depending on the calendar year in which the EP first began attesting. Prior to 2015, there were three distinct Stages for the MU program.[37] However, on October 16, 2015, the Stage 3 final rule was published.[38] This new rule substantially revised the MU program, consolidating Stages 1 and 2 into a single Modified Stage 2. Beginning in 2015, EPs are required to report on a single set of objectives and measures. For 2015, the reported period will be any continuous 90-day period, and all EPs have until February 29, 2016 to attest.[39] After this point, the reporting period depends on whether the EP has previously participated in the MU program. Those who have must report for a full year, while those who have not may report for any continous 90-day period within the calendar year.[40] In 2017, the reporting period is a full year for all EPs, regardless of whether they have reported previously.[41]

As part of the Stage 3 final rules, beginning in 2015, EPs must report on ten objectives, using clinical quality measures (CQMs).[42] The type of information reported under MU is similar

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[37] For an examination of the MU program in previous years, see Shay, Daniel F., PQRS and its Penumbra, HEALTH LAW HANDBOOK, 2012 ed., pp. 87-119.

[38] 80 Fed. Reg., 62762, October 16, 2015. For general guidance on what has changed with the promulgation of the Stage 3 final rule, CMS has published a helpful guide, titled ñEHR Incentive Programs: Whatôs Changed for EHR Incentive Programs in 2015 through 2017 (Modified Stage 2),ò available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2015_Stage2ComparisonFactSheet.pdf.

[39] 80 Fed. Reg. 62779; 62896-62897, October 16, 2015.

[40] 42 CFR § 495.4.

[41] 42 CFR § 495.4.

[42] These objectives are: (1) protect patient health information; (2) clinical decision support; (3) computerized

to that reported under PQRS, albeit not always identical. Data under MU is reported as ñclinical quality measuresò (CQMs). In years past, CQMs could overlap much more easily with QDCs under PQRS. However, with the Stage 3 final rule, many of the independent measures that overlapped (such as recording smoking status under MU, and several QDCs relating to smoking status) have now been consolidated into general measures (e.g., information about smoking status must be included in the patientôs record, which must be provided to the patient under Measure 2 of the Patient Electronic Access objective).[43] Some measures remain consistent, however. For example, EPs must still attest that they have performed a security risk assessment during the reporting year.[44] In recent years, CMS has begun to audit EPs who attest under MU, and has begun demanding repayments of MU incentive payments for those EPs who fail to meet all of the requirements for payment.[45]

Reaction to the Stage 3 final rule has been less than positive. One of the major issues in transitioning from two distinct Stages to Modified Stage 2 is that some physicians were still only expected to comply with the requirements of Stage 1, rather than the more stringent requirements of Stage 2. In light of this fact, CMS included multiple alternative reporting options and exemptions, and also suggested that those EPs who could not meet the 2015 requirements apply

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provider order entry; (4) electronic prescribing; (5) health information exchange; (6) patient specific education; (7) medication reconciliation; (8) patient electronic access; (9) secure electronic messaging; and, (10) public health reporting. 42 CFR § 495.22(e).

[43] 80 Fed. Reg. 62812, 62815, October 16, 2015. See also, ñEHR Incentive Programs: Whatôs Changed for EHR Incentive Programs in 2015 through 2017 (Modified Stage 2),ò Appendix A, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/2015_Stage2ComparisonFactSheet.pdf.

[44] 42 CFR § 495.22(e)(1)(ii)(A). For more on security risk assessments both with respect to the MU program and under HIPAA, see Shay, ñHIPAA and Meaningful Use Audits and the Security Risk Analysis Nexus,ò HEALTH LAW HANDBOOK, 2015 ed., pp. 429-464.

[45] To date, however, CMS does not appear to have imposed retroactive payment adjustments as the result of a failed audit. ***[CHECK again when galleys come back.]***

for hardship exemptions. The American Medical Association supported CMSô allowance of hardship exemptions for physicians who could not attest in 2015, but stated, ñThe AMA continues to believe that stage 3 requires significant changes to ensure successful participation, and improve the usability and interoperability of electronic health record systems.ò[46] Kim Allan Williams, Sr., M.D., F.A.C.C., president of the American College of Cardiology, stated,

> ñ*While we applaud CMS for finalizing programmatic changes to the 2015-2017 reporting years, that should ease the difficulties providers face when attempting to meet meaningful use requirements, the decision to combine meaningful use into one single stage and finalize the program requirements at this time remains difficult to implement. Many of the requirements for stage 2 proved unattainable.*ò[47]

The Chairman of the Senate Health Committee, Lamar Alexander (R-TN), stated ñInstead of taking the time to get the stage 3 rule right, theyôve rushed ahead when only 12 percent of doctors and less than 40 percent of hospitals can comply with the programôs stage 2.ò[48] Senator Alexander further indicated that Congress would ñcarefully reviewò the final rule, and would either attempt to pass new legislation to change it, or overturn it using the Congressional Review Act. To date, no such action has been taken.

Finally, with respect to payment, CMS offers payment incentives from 2011 through 2016 to EPs who successfully attest to meaningful use of certified EHR technology.[49] Beginning

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[46] Stack, Steven, M.D., President, American Medical Association, ñMeaningful Use Regulations Represent Progress, but More Work to be Done,ò press release, October 6, 2015, available at, http://www.ama-assn.org/ama/pub/news/news/2015/2015-10-06-statement-meaningful-use-regulations.page.

[47] Williams, Kim Allan, Sr., M.D., F.A.C.C., ñAligning All Stages of Meaningful Use Ignores Difficulties Faced By Providers,ò press release, October 7, 2015, available at, https://www.acc.org/about-acc/press-releases/2015/10/06/17/23/acc-aligning-all-stages-of-meaningful-use-ignores-difficulties-faced-by-providers?w_nav=S.

[48] Alexander, Lamarr, ñAlexander: Rushing Stage 3 Rule of Electronic Health Records Program a óDisservice to More than 500,000 Doctors, Thousands of Hospitals and Millions of Patients,ôò press release, October 6, 2015, available at, http://www.alexander.senate.gov/public/index.cfm/pressreleases?ID=cf76d36e-9306-458e-8c6d-26c0f1a92a14.

[49] Payment amounts vary, and depend on which year an EP first attested to meaningful use. For example, in 2011,

in 2016, however, this will end. In 2015, the MU program also began to impose payment adjustments for those EPs who failed to properly attest, or who did not participate at all.[50] The adjustments took the form of a 1% reduction for all Medicare payments, imposed on an annual, cumulative basis for every year that the EP fails to properly attest or participate, although that amount increases to a 3% reduction for 2018.[51] In years past, the MU program operated on the same 2-year ñlagò that other reporting programs did. With the promulgation of the Stage 3 final rule, however, that period is reduced to a 1-year ñlag.ò Accordingly, data reported in 2015 forms the basis for 2016 payment adjustments; data reported in 2016 forms the basis for 2017 payment adjustments, and so on.[52]

2.4 Value Based Payment Modifier

The Value Based Payment Modifier (VPM) was created with the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA).[53] The modifier went ñliveò in 2015. When regulations governing the VPM were initially published in the 2013 Medicare Physician Fee Schedule, the VPM only applied to large groups of 100 or more EPs.[54] Over the years, CMS has imposed the VPM on progressively smaller groups. In the 2014 Medicare Physician Fee

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the payment amount was $18,000. In 2016, the payment amount is either $1,960, or $3,920, depending on whether the EP first successfully attested to meaningful use in 2012, 2013, or 2014. There are no incentive payments for EPs who did not successfully attest to meaningful use after 2014. For a chart breaking down the amount of payments by reporting year, see https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/basics.html.

[50] 42 CFR § 495.102(d).

[51] 42 CFR § 495.102(d).

[52] For a helpful chart describing reporting years and payment adjustment years for EPs, see 80 Fed. Reg. 62906, October 16, 2015.

[53] PPACA § 3007.

[54] 77 Fed. Reg. 69308, November 16, 2012. Although, CMS initially proposed that VPM be applied to groups of 25 or more, it walked back this approach for VPMôs initial year.

Schedule, the VPM was applied to groups of 10 or more, and subsequently to groups of 2 or more in the 2015 Medicare Physician Fee Schedule.[55] Beginning in 2018, CMS will apply the VPM to non-physician individual EPs and groups with non-physician practitioners, based on reporting data collected in 2016, although it will only be applied to non-physician EPs who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists.[56] As mandated by PPACA, the VPM itself is also intended to be coordinted with other value-based purchasing reforms, such as the Hospital Value-Based Purchasing program.[57]

For purposes of the VPM, EPs are determined based on a review of information contained in the CMS database for Medicare credentialing.[58] Physicians, non-physician practitioners, and groups therefore have another incentive to keep their PECOS information up-to-date, since it will be this information that CMS will use as the basis for applying the VPM to them. Interesingly, CMS determines the size of a group based on both a review of the PECOS information, and on its own analysis of claims data. Recognizing that there could be discrepancies between those numbers, however, as of 2016, CMS has taken the position that it will base group size on the lower of the two numbers.[59]

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[55] 78 Fed. Reg. 74766, December 10, 2013; 79 Fed. Reg. 67932, November 13, 2014, respectively.

[56] 80 Fed. Reg. 71278, November 16, 2015. Moreover, these individuals will be held harmless from any downward adjustment in payment, as discussed below in this section, although these non-physician EPs will still be subject to the downward adjustment if they are in groups with physician EPs; the held-harmless provision only applies to solo non-physician EPs and those in groups with non-physician EPs only.

[57] 42 U.S.C. 1395wï 4(p)(9). The Hospital Value Based Purchasing program (VBP) is a distinct program from the VPM, codified under a different section of PPACA. Although the two programs share some similarities, this article focuses solely on the physician experience. For a discussion of the Hospital VBP, see Shay, Daniel F., PQRS and its Penumbra, HEALTH LAW HANDBOOK, 2012 ed., pp. 87-119.

[58] Known as the Provider Enrollment Chain and Ownership System, or PECOS. See, https://pecos.cms.hhs.gov/pecos/login.do.

[59] 80 Fed. Reg. 71276, November 16, 2015. The implication of this policy is that, where there is a discrepancy between the two methods for determining group size, CMS will consider the group to be smaller. Historically

The VPM is applied to EPs based on the PQRS data that EPs report, and all of the measures reported under PQRS are used as measures in VPM.[60] Because the VPM relies upon data reported through PQRS, it too operates on a 2-year ñlagò for application of payment adjustments.[61] Thus, data reported in 2016 forms the basis for the application of the 2018 VPM payment adjustments.

In addition, VPM adds three quality measures (also referred to as outcomes measures): (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease (COPD), and diabetes (including uncontrolled diabetes, short term and long term diabetes complications, and lower extremity amputations); (2) a composite of rates of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; (3) and rates of an ñall-causeò hospital readmissions measure.[62] The VPM also includes cost measures, which are based on a composite made up of six cost measures: (1) total per capita costs for all attributed beneficiaries; (2) total per capita costs for all attributed beneficiaries with diabetes; (3) total per capita costs for all attributed beneficiaries with coronary

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speaking, being treated as a smaller group has meant that the group is generally more protected from the potential deleterious effects of the VPM. While this distinction is less relevant these days, if a similar approach is taken with MIPS, it could mean the difference between whether a group is subject to downward payment adjustment at all, or whether the group is ñheld harmlessò from such adjustments.

[60] 42 CFR § 414.1220, which states that all solo practitioners and groups that are subject to the VPM may report using whatever methods they are permitted to use under PQRS. 42 CFR § 414.1225 also incorporates the quality measures used under PQRS into the data reported for VPM.

[61] CMS explained in the preface to the 2013 Medicare Physician Fee Schedule that ñé we explored different options to close the gap between the performance period (that is, 2013) and the payment adjustment period (that is, 2015), but found that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate a value-based payment modifier and notify physicians and groups of physicians of their quality and cost performance and value-based payment modifier prior to the payment adjustment period.ò 77 Fed. Reg. 69313-69314, November 16, 2012.

[62] 42 CFR § 414.1230. However, the ñall-causeò readmissions measure does not apply to groups of 2-9 EPs or solo practitioners, starting with the 2017 payment adjustment period.

artery disease; (4) total per capita costs for all attributed beneficiaries with COPD; (5) total per capita costs for all attributed beneficiaries with heart failure; and (6) Medicare Spending per Beneficiary associated with an acute inpatient hospitalization.[63] However, all of this information is derived from PQRS data.

CMS further benchmarks the quality of care measures by deriving a national mean for the measureôs performance rate during the year prior to the performance period.[64] The benchmark that will be applied to quality measures reported in 2016, and subject to payment adjustment in 2018, will be based on data submitted in *2015*. Cost measures are similarly benchmarked, as a national mean of the performance rates calculated among all groups and solo EPs that meet the minimum number of cases for that measure.[65] Generally speaking, in calculating the national benchmarks, the performance rates for solo practitioners and groups (or EPs within the group) are weighted by the number of beneficiaries used to calculate the solo practitionerôs or groupôs performance rate.[66]

After determining the benchmark scores for quality and cost measures, CMS takes a composite of the EP or groupôs quality and cost measures and compares them to the national mean for each. For quality measures, composites that are one or moer standard deviation(s) above the mean are treated as ñhigh quality,ò while those one or more standard deviations below

[63] 42 CFR § 414.1235(a). These m easures are adjusted, however, to standardize payments across geographic regions, to take into account the patientôs age and severity of illness, and to account for a groupôs specialty mix by computing a weighted average of the national specialty specific expected costs and comparing the groupôs actual risk-adjusted costs to that number. See, 42 CFR § 414.1235(c).

[64] 42 CFR § 414.1250.

[65] 42 CFR § 414.1255. This number is generally 20 or more cases for the measure, although the minimum for the all-cause hospital readmissions measure is 200 cases, and the minimum for the Medicare Spending Per Beneficiary measure is 125 episodes. If there are insufficient numbers of cases or episodes, the measure is excluded from the composite score calculation, which is discussed further below. 42 CFR § 414.1265.

[66] 42 CFR §§ 414.1250; 414.1255.

the mean are treated as ñlow quality.ò[67] Similarly, for cost measures, composites that are one or more standard deviation below the mean are classified into the ñlow costò category, while tose one or more standard deviations above the mean are classifeid into the ñhigh costò category.[68] CMS then compares an EP or groupôs costs category against its quality category, and applies a final payment adjustment score to the EP or group. This breakdown of quality vs. costs and the resulting score is referred to as ñquality tiering.ò

Initially, the ñquality tieringò method was optional. However, in 2014, CMS made this approach mandatory.[69] The approach to quality tiering has varied, based on group size. For example, in 2014, quality tiering became mandatory for all groups of 10 or more, but groups of 100 or more would face upward, neutral, or downward payment adjustments, while groups of 10-99 only faced neutral or upward adjustment.[70] By 2015, quality tiering was mandatory for all EPs and groups of 2 or more, although solo practitioners and groups of 2-9 EPs were only subjected to neutral or upward payment adjustments, and groups of 10 or more were subjected to downward, neutral, or upward payment adjustments.[71]

CMS has taken a similar approach with respect to the amount of negative payment adjustments. As each new group of professionals has been subjected to downward adjustments, CMS has typically ñheld harmlessò the newest group. By way of example, in 2014, when downward adjustments were first applied to groups of 10 or more, groups who voluntarily

[67] 42 CFR § 414.1275(b)(1).

[68] 42 CFR § 414.1275(b)(2).

[69] 78 Fed. Reg. 74769, December 10, 2013.

[70] 78 Fed. Reg. 74770, December 10, 2013.

[71] 79 Fed. Reg. 67941, November 13, 2014.

reported were held harmless from downward adjustment, even if they fell below the quality threshold.[72]

For data reported in 2016, which will form the basis for 2018 payment adjustments, the amount of adjustment will depend on whether the reporting entity is (1) a group of 10 or more EPs; (2) solo physicians, and physicians, PAs, NPs, CNSs, or CRNAs in a group with other physicians of 2-9 EPs; and (3) PAs, NPs, CNSs, CRNAs in groups of non-physician EPs, and solo practitioners who are PAs, NPs, CNSs, or CRNAs. The amount of payment adjustment for each of these groups is as follows: [73]

- **Groups of 10+ EPs (including PAs, NPs, CNSs, or CRNAs):**

Cost/Quality	**Low quality**	**Average quality**	**High quality**
Low cost	+0.0%	+2.0x	+4.0x
Average cost	-2.0%	+0.0%	+2.0x
High cost	-4.0%	-2.0%	+0.0%

- **Solo physicians, and physicians, PAs, NPs, CNSs, or CRNAs in a group with other physicians of 2-9 EPs:**

Cost/Quality	**Low quality**	**Average quality**	**High quality**
Low cost	+0.0%	+1.0x	+2.0x
Average cost	-1.0%	+0.0%	+1.0x
High cost	-2.0%	-1.0%	+0.0%

[72] 79 Fed. Reg. 67934, November 13, 2014.

[73] 42 CFR § 414.1275(c)(4).

- **PAs, NPs, CNSs, CRNAs in groups of non-physician EPs, and solo practitioners who are PAs, NPs, CNSs, or CRNAs:**

Cost/Quality	Low quality	Average quality	High quality
Low cost	+0.0%	+1.0x	+2.0x
Average cost	+0.0%	+0.0%	+1.0x
High cost	+0.0%	+0.0%	+0.0%

Astute observers will note the difference between negative and upward payment adjustments and how they are applied. Unlike downward adjustments, upward adjustments function as a multiplier of a predetermined value modifier, rather than a percentage of Medicare payments, and depend on the quality of care provided. The amount of upward adjustment has also increased over time.[74]

At least in recent years, CMS has not been of the opinion that VPM has a significant impact. Data cited by CMS indicated that only a small percentage of EPs fell below or rose above the threshold to where they received either downward or upward payment adjustments; most EPs simply stayed at the ñaverageò level. For groups of 25 or more EPs, CMS stated that slightly more than 8% were expected to earn upward adjustments. Less than 11% of groups of 25 or more EPs would earn downward adjustments. For groups of 100+, only 5.5% would earn upward adjustments (68 out of 1236), and 7.1% would earn downard adjustments (88 out of 1236).[75] Although this information is derived from 2012 data, it illustrates that CMS itself views

[74] Initially, the highest upward adjustment was +2.0x. 77 Fed. Reg. 69324, November 16, 2012. This increased to +4.0x in the 2015 Medicare Physician Fee Schedule. 79 Fed. Reg. 67953, November 13, 2014.

[75] 78 Fed. Reg. 74769, December 10, 2013.

the VPM as neither much of a carrot nor a stick in terms of spurring greater quality or value.

2.5 Physician Compare

As with the VPM, the Physician Compare website was created with the passage of PPACA.[76] Physician Compare functions as a web page on the Medicare.gov site, which displays a range of information on physicians who participate in Medicare. This information includes demographic data (such as name, address, practice name(s), and specialty), but also educational information (such as where the physician attended medical school and did their residency program), and information on the physicianôs participation in certain quality programs (such as PQRS, Meaningful Use, etc.). In 2011, information regarding PQRS participation and other quality-related data was only viewable by the individuals covered by the information or the groups in which they worked and reported information. However, as required by PPACA, this information was made available to the public. CMS has publicly stated that the purpose of the Physician Compare site is to create transparency and to provide consumers with useful information to assist them in selecting a physician. ñThe primary goal of Physician Compare is to help consumers make informed health care decisions.ò[77]

The website, which is admittedly a work in progress, has faced criticism, too. In 2014, Shari Erickson, MPH, Vice President for Governmental and Medical Practice of the American College of Physicians, stated that, while the Physician Compare website was displaying measures that were well-validated, the website needed additional context for the data available on the site, to better allow patients to understand the importance of the measures displayed. Similarly, Reid Blackwelder, M.D., then-president of the American Academy of Family

[76] PPACA § 10331.

[77] 80 Fed. Reg. 41809, July 15, 2013.

Physicians, stated that "[Physician Compare]'s usability in general is less than friendly, but CMS' spirit of quality measurement and transparency is sound," and described the then-current implementation and available data to be "flawed, but repairable."[78]

3. The New Landscape: MIPS

As discussed above, CMS has found that programs such as VPM have had relatively little impact on the quality or value of care provided by participating professionals. Given the demographic pressures the Medicare system faces in the ever-nearing future, the system must change and adapt. Towards this end, the Merit-Based Incentive Payment System (MIPS) represents both a major change in, and evolution from, the status quo. This new system fundamentally alters how payment functions, but in ways that will likely appear familiar to physicians. Per MACRA, MIPS must ñgo liveò by January 1, 2019, and regulations for MIPS must be published by no later than November 1, 2018. Although no regulations have yet been published ***[or even proposed – Check again when galleys come out]*** at the time of this writing, we do know some information about how MIPS will function, based on what appears in the text of MACRA, and on changes to CMSôexisting regulations. By examining this information, we can see that MIPS will contain much which is the same or similar to what has come before, but will also differ substantially from previous approaches to payment.

3.1 Building on the Past

Three separate, independent programs will sunset in 2018 just prior to MIPS going live: PQRS, MU, and VPM. However, these programs only end as *individual* programs; they will be incorporated into MIPS for purposes of measuring professionals. The programs will continue as parts of a whole, and data reported in 2017 will be analyzed for purposes of payment adjustments

[78] http://www.modernhealthcare.com/article/20140221/NEWS/302219939.

to EPsô Physician Fee Schedule payments in 2019.[79] It will therefore be incumbent upon professionals to make certain that the data they submit continues to meet the requirements for these programs (even as those requirements change over time).

The new system will encourage the use of both EHRs and QCDRs as mechanisms for reporting quality measures, and the Secretary of Health and Human Services is expected to incentivize their use.[80] One can speculate that this may occur in several ways. For example, CMS could phase out other reporting methods over time. Alternatively, CMS could impose penalties on the use of non-preferred reporting methods, and/or could offer additional upward adjustments for the adoption and use of preferred methods. This could be implemented either through an additional ñfinger on the scaleò calculation in MIPS itself, or as an additional percentage for upward or downward adjustment which factors in after MIPS calculation. To understand how all of this will work, however, one must explore the very different method by which payment to professionals is made under MIPS.

3.2 Something New and Different

Under traditional Medicare and the fee-for-service payment model, healthcare has been paid for like ñwidgets.ò By performing more services, a professional makes more money (medical necessity determinations, and fraud and abuse laws notwithstanding). Previous systems such as PQRS or Meaningful Use paid more for the mere reporting of information, rather than actual outcomes. A failure to report would reduce a professionalôs overall payments, but the professional was still fundamentally paid based on the volume and value of the services

[79] Meaningful Use is continued under 42 USC § 1395w-4(o)(2)(D). PQRS is continued under 42 USC §§ 1395w-4(k)(9) and 1395w-4(m)(9). VPM is continued under 42 USC § 1395w-4(p)(2)(C).

[80] The text explicitly reads ñUnder the MIPS, the Secretary shall encourage the use of qualified clinical data registriesé ò 42 USC § 1395w-4(q)(1)(E).

performed. The Value-based Payment Modifier attempted to apply value to the performance of services, and MIPS will operate under a similar, but not identical, approach.

Like the VPM, MIPS will develop a composite performance score for each professional. This score will range from 0 to 100[81] and will be based on four types of measures: quality, resource use, clinical practice improvement activities, and meaningful use of certified EHRs.[82] Quality measures will be weighted at 30% of the professionalôs total score, and will likely be based, at least initially, on PQRS measures.[83] Resource use will be weighted at 30%, generally, but for the first two years of the program will not be permitted to go above 10% and 15%, respectively.[84] Meaningful use of certified EHRs will be weighted at 25%[85], although the Secretary of Health and Human Services shall be permitted to adjust this amount, for example if there is a stampede to adopt EHRs.[86]

Clinical practice improvement activities will be weighted at 15%.[87] These include: (1) expanded practice access (e.g., same-day appointements, or after-hours visits); (2) population management (e.g., monitoring health conditions to perform timely interventions, and

[81] 42 USC § 1395w-4(q)(5)(A).

[82] 42 USC § 1395w-4(q)(2)(A)(i)-(iv), respectively.

[83] 42 USC § 1395w-4(q)(5)(E)(i)(I)(aa).

[84] 42 USC § 1395w-4(q)(5)(E)(i)(II). In the first two years, the Secretary is required to increase the percentage weight for quality measures by however much the resource use measures are reduced. So, if resource use measures are weighted at only 8% in a year, quality measures will be weighted at 52%.

[85] 42 USC § 1395w-4(q)(5)(E)(i)(IV).

[86] 42 USC § 1395w-4(q)(5)(E)(ii). The text specifically reads, ñIn any year in which the Secretary estimates that the proportion of eligible professionalsé who are meaningful EHR usersé is 75 percent or greater, the Secretary may reduce the percent applicable under clais (i)(IV), but not below 15 percent. If the Secretary makes such reduction for a yearé the percentages applicable under one or more of subclauses (I)(II), and (III) of clause (i) for such year shall be increased in a manner such that the total percentage points of the increase under this clause for such year equals the total number of percentage points reduced under the preceding sentence for such year.ò

[87] 42 USC § 1395w-4(q)(5)(E)(i)(III).

participation in QCDRs); (3) care coordination (e.g., communicating test results to, and exchanging clinical information with, patients and professionals, as well as the use of telemedicine); (4) beneficiary engagement (e.g., estabilishing plans of care for individuals); (5) patient safety and practice assessment (e.g., use of surgical checklists); and, (6) participation in alternative payment models (APMs).[88] A failure to report a measure under MIPS will result in the professionals receiving the lowest possible score for the reported measure.[89] However, participation as a patient-centered medical home could yield the highest score for the measure, and participation in an APM will yield 50% of the highest possible score for the measure.[90]

Each groupôs or EPôs composite score will be compared to an annually established national performance threshold.[91] Every three years, the Secretary of Health and Human Services will decide whether to set the threshold to a median of composite performance scores for all MIPS EPs, or a mean.[92] This median or mean will be based on a period previously specified by the Secretary.[93] There will also be an ñadditional performance thresholdò (discussed further below), which will be equal to either the 25th percentile of the possible composite performance scores above the performance threshold, or the 25th percentile of the actual composite performance scores above the threshold during the prior period.[94] This will create a ñmoving targetò for both quality and value. Under MIPS, there will always be winners and

[88] 42 USC § 1395w-4(q)(2)(B)(iii).

[89] 42 USC § 1395w-4(q)(5)(B)(i).

[90] 42 USC § 1395w-4(q)(5)(C)(i) and (ii), respectively.

[91] 42 USC § 1395w-4(q)(6)(A).

[92] 42 USC § 1395w-4(q)(6)(D)(i).

[93] 42 USC § 1395w-4(q)(6)(D)(i).

[94] 42 USC § 1395w-4(q)(6)(D)(ii).

losers, and the payments not made to the losers will ultimately provide the money that is paid to the winners. This also means that CMS will have an incentive to find more losers than winners.

Both upward and downward adjustments will be based on a percentage. In 2019, this amount will be 4%. In 2020, it will be 5%, then 7% in 2021, and 9% for 2022 and beyond.[95] Reporting EPs who perform at or above the threshold will receive either no change to their payment, or a positive payment (which is capped based on the EPôs composite score).[96] A score exactly at the threshold will receive a 0 and results in no change in payment.[97] A score of 100 will receive 100% of the possible upward adjustment. A score between 0 and 100 will receive a proportional amount of the total upward adjustment. Exceptional performance may lead to additional adjustments between 2019 and 2024.[98] A negative payment adjustment will be applied to EPs who perform below the threshold, on a linear scale.[99] However, score between 0 and ¼ of the threshold will have the full negative amount applied.[100]

To put this into context, consider the following scenario. In 2020, the Secretary determines that the upward adjustment factor will be 1.5x, and the MIPS performance threshold will be a composite score of 65. If a professionalôs score is above 65, they will receive either no adjustment or an upward adjustment. If the professionalôs score is below 65, they will receive a

[95] 42 USC § 1395w-4(q)(6)(B). MIPS also includes a ñscaling factor,ò which permits CMS to multiply these scores ï upwards or downwards ï but up to a factor of three. In other words, a theoretical high-performing professional in 2021 could receive a 21% upward payment adjustment, provided that the downward payment adjustments that year were enough to allow budget neutrality. Scaling factors are addressed at 42 USC 1395w-4(q)(6)(E) and (F).

[96] 42 USC § 1395w-4(q)(6)(A)(ii)(I).

[97] 42 USC § 1395w-4(q)(6)(A)(iii).

[98] 42 USC § 1395w-4(q)(6)(A)(iii).

[99] 42 USC § 1395w-4(q)(6)(A)(iv)(I).

[100] 42 USC § 1395w-4(q)(6)(A)(iv)(II).

negative adjustment. Dr. Smithôs composite score is 50, so Dr. Smith will receive a downward payment adjustment. Because the downward adjustment is 5% in 2020, Dr. Smithôs payment adjustment will be -3.85%. By contrast, Dr. Jonesôcomposite score is 12, which falls within the 0-¼ range, meaning that Dr. Jones will receive a full -5% downward adjustment. Dr. Tanakaôs composite score is 70, so Dr. Tanaka will receive a +0.7% upward adjustment.[101]

In addition, professionals ' MIPS performance will be reported on the Physician Compare website, displaying the EPôs composite score under MIPS, and the EPôs performance score in each performance category.[102] There will be no formal appeals process available to professionals. As required by the explicit language of MACRA, professionals will not permitted to appeal: (1) the methodology of the MIPS adjustment factor or the amount of additional MIPS adjustments; (2) the performance standards or performance period for MIPS; (3) the selection of measures or activities that are required for MIPS performance; or (4) the methodology for calculating MIPS performance scores and weighting calculations.[103] The statute does require the Secretary to ñestablish a process under which a MIPS eligible professional may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to such eligible professionalò for that year.[104]

4. <u>Pitfalls and Remedies</u>

All of these programs have pitfalls for physicians. In addition to being complex, easily misunderstood, and harmful to a physicianôs bottom line (if the physician fails to properly

[101] Dr. Tanakaôs composite score would need to be 100 to receive the full +5% upward adjustment.

[102] 42 USC § 1395w-4(q)(9). The website may also include information regarding the EPôs performance in each *measure or activity* required under MIPS.

[103] 42 USC § 1395w-4(q)(13).

[104] 42 USC § 1395w-4(q)(13).

report), Medicareôs quality programs also generally lack any kind of formal appeals process. Improper reporting under these programs can also create significant liability under the Federal False Claims Act.[105] Lastly, although we still do not know the full contours of MIPS, we can guess at the potential future problems posed by such a system.

4.1 Appeals (or Lack Thereof) and Informal Reviews

As discussed above, the MACRA statute prohibits judicial review of fundamental decisions in the MIPS program. The same is true for the programs which will form the basis for MIPS.[106] Professionals, therefore, will lack any avenue to appeal to an administrative law judge, nor to a federal district court or beyond; instead, they will be limited to whatever internal administrative processes CMS deigns to offer. These processes typically take the form of what CMS referrs to as an "informal review."

The available "informal review" options differ, depending on the system. For PQRS, according to CMS, the informal review process for payment adjustments applied in 2016[107] only looked at the data reported from January 1, 2014 ï December 31, 2014.[108] The informal review process was available for all of the 2014 reporting mechanisms.[109] When an informal review request was received by CMS, CMS investigated whether the requesting entity met the

[105] 31 USCA § 3729.

[106] 42 CFR § 414.90(n); 42 CFR § 405.110; 42 CFR § 414.1280.

[107] At the time of this writing, CMS had not yet published guidance on how the informal review process would work for adjustments applied in 2017 or 2018.

[108] Although, EPs who reported via claims for 2014 PQRS may request an informal review of QDCs submitted and processed into the National Claims History file by February 26, 2015 for inclusion in 2014 PQRS incentive eligibility analysis.

[109] Including: claims (for individual EPs only); qualified registries; qualified EHRs either through direct data submission or submission by the vendor; QCDR (for individual EPs only); GPRO Web Inerface (for groups of 25+); and CAHPS for PQRS summary survey modules (for groups of 25+ to supplement their GPRO reporting.

requirements for satisfactorily reporting in 2014. The request for informal review had to be submitted through CMSô Quality Reporting Communication Support Page (CSP) between September 9, 2015 and December 11, 2015.[110] Professionals were instructed to complete the mandatory fields on the online form and include appropriate justification for the request. The requesting professional would receive a confirmation email of receipt of the request, and would be notified of a decision by CMS within 90 days of submission of the original request for review. The decision was final; no further appeals would be made available. ***[Will check when galleys come back to see if they posted any info on overall results. It just closed last Friday.]***

Informal reviews under the VPM have followed a similar process.[111] In September, 2015, CMS made available the 2014 Annual Quality and Resource Use Reports (QRURs) for all group practices and solo practitioners.[112] For groups with 10 or more EPs, the QRUR showed how the VPM would apply to the groupôs physician payments under the Medicare Physician Fee Schedule for physicians billing through the groupôs tax ID number (TIN) in 2016. Once the QRURs were released, CMS gave groups 60 days[113] to request a correction of any perceived

[110] Interestingly, as part of an increased reliance on informal communication, CMS announced the availability of the web page for informal review requests through its Medlearn Matters Network Connects Provider eNews service, its PQRS Listserv, and ñother related CMS listservs.ò P.4. For additional discussion of CMSôreliance on these mechanisms to both inform and regulate, see Gosfield, Alice G., ñBeyond Face Time: The Evolution of Medicare fee For Service in a Value Driven World,ò HEALTH LAW HANDBOOK, 2016 ed.

[111] For a more in-depth description, see CMSô ñ2016 VM Informal Review Request Quick Reference Guide,ò at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2014-VM-Informal-Review-Request-Quick-Reference-Guide.pdf.

[112] A sample 2014 QRUR may be found at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2014-Sample-Annual-QRUR.pdf. For additional information on 2014 QRURs, see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2014-QRUR.html. For 2013 QRUR information, see https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/2013-QRUR.html.

[113] The last day to request an informal review was November 9, 2015. ñHow to Meet Quality Reporting Requirements, Earn Incentives, and Avoid Negative/Downward Payment Adjustments in 2017 for CMS Medicare Quality Programs,ò CMS Slide Deck, September 24, 2015, p.23, at https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2015-09-24-PQRS-Slide-Presentation.pdf.

error. This could be done through several different online mechanisms.[114] In general, the groupôs designated representative would then select from a pre-determined list of reasons for their informal review request,[115] after which the representative could enter a justification for requesting the review (limited to 1500 characters), with the option to attach exhibits. Groups could request an informal review for multiple reasons. After this information was submitted, the group representative would attest to the truth of the information submitted, and submit the request.

Physician Compare does not have any true ñappealsò process. Rather, there are options for physicians to update and/or correct inaccuracies in their information. According to CMS, Physician Compare populates its data on physicians based on a bi-monthly examination of data from PECOS and claims submissions. Physicians do have the ability to update and revise the information about them on PECOS (and thus, what appears on Physician Compare), although edits made in PECOS can take from two to four months to process.[116] Most changes that Physician Compare permits are to demographic information, and are updated through PECOS.[117] Therefore, a female physician who was erroneously listed as male may update her information in

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[114] Specifically, through the PV Landing Portlet, the CMS Enterpise Secure Portal, or the QualityNet Customer Support Page.

[115] The reasons offered are general categories: Group Size, QRUR Cost, QRUR Quality, QRUR Other, Registration, and Other. See, ñ2016 VM Informal Review Request Quick Reference Guide,ò p. 11, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/2014-VM-Informal-Review-Request-Quick-Reference-Guide.pdf.

[116] See,CMS FAQ: ñHow often is Physician Compare updated?ò at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/How-to-Update-your-Data-on-Physician-Compare.html#How%20often%20is%20Physician%20Compare%20updated?.

[117] See, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/How-to-Update-your-Data-on-Physician-Compare.html. The same is true of group practices; most information is culled from PECOS, and can be updated through PECOS. Physician Compare will automatically display a groupôs ñdoing business asò name on the Physician Compare website, since it is the most likely to be recognized by consumers, rather than the groupôs legal business name.

PECOS, and the change will be reflected on the Physician Compare website once it is processed by PECOS. Factual errors can be reported to the Physician Compare Support Team[118], but there are no formal mechanisms for otherwise disputing information appearing on the website.

Similarly, although Meaningful Use does include a hardship exception, the exception is limited. The regulations themselves state that the exception may be applied ñon a case-by-case basisò under certain circumstances. The exception is only available: (1) when the EP was located in an area with insufficient internet access to participate in the MU program; (2) the EP has been practicing less than 2 years; (3) the EP faced ñextreme and uncontrollable circumstancesò preventing the EP from being a meaningful EHR user; or, (4) the EP practiced at multiple locations and could not control the availability of certified EHR software at one or more practice locations, when such locations represent 50% or more of the EPôs patient encounters, the EP cannot meet MU requirements due to a lack of face-to-face encounters or telemedicine interaction with patients; or the EP is an anesthesiologist, radiologist, or pathologist.[119] In most cases, the EP must submit an application for a hardship exception, although some EPs are granted automatic exemptions.[120]

Like the other ñinformal reviewò processes, the MU regulations explicitly prohibit

[118] Available at PhysicianCompare@Westat.com, according to the ñPhysician Compare Administrative Information Sheet,ò located at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/Downloads/Physician-Compare-Administrative-Information-Fact-Sheet.pdf.

[119] 42 CFR § 495.102(d)(4).

[120] The following EPs do not have to submit hardship exceptions: (A) new practitioners in their first year of practice; (B) EPs who are hospital-based (meaning that they provide more than 90% of their professional services in inpatient settings or emergency departments of hospitals); (C) EPs who list a primary specialty of anesthesiology, pathology, diagnostic radiology, nuclear medicine, or interventional radiology on their PECOS records during the six months prior to the first day of patment adjustments. https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship.html.

judicial review of the methodology for determining eligibility for hardship exceptions.[121] Moreover, none of the other quality initiative programs includes a hardship exception. At best, professionals are shielded from downward adjustments in their initial year under the VPM. The only other avenue is the informal review processes discussed above.

4.2 False Claims Liability Under Current Programs

Medicareôs quality programs all rely on the reporting of data as a condition of payment. Therefore, they all fall within the crosshairs of the federal False Claims Act (FCA). The precise application of the FCA to these types of programs is complicated, however, and depends on the progam. With incentive-based payments, one problem scenario could occur where a professional receives money, and later discovers that it has reported erroneously. This is more likely to occur with programs like Meaningful Use, where payment is a fixed amount that is entirely conditional upon successful attestation. However, a similar problem could occur with respect to positive payment adjustments under both the VPM and MIPS. In these cases, the professional would have to return overpayments within 60 days of discovery. Failure to do so would implicate the FCA.[122]

The global nature of these programs also presents a problem for purposes of calculating the amount of any false claims. Meaningful Use incentive payments represent individual, fixed payments;[123] therefore, determining damages under the FCA is relatively simple. The absolute maximum amount of damages would be triple the amount of the incentive payment itself, plus

[121] 42 CFR § 495.110(a)(4).

[122] 31 USCA § 3729. The FCA, as modified by the Fraud Enforcement Recovery Act of 2009, and later PPACA, made retention of overpayments 60 days after the provider knew or reasonably should have known of the existence of the overpayment a false claim.

[123] See above, at note ***45.***

$11,000. However, negative payment adjustments ï under any of the above-mentioned programs ï necessitate a more complicated analysis.

The fact pattern that would give rise to the most damaging false claims exposure would involve a professional who knowingly submitted false quality reporting data and *avoided* a negative payment adjustment. First, the act of submitting the false quality data would itself be a false claim. However, the avoidance of negative payment adjustments would mean that *every claim submitted by the professional* during the period when the negative payment adjustment should have applied would be treated as a retained overpayment, and thus a false claim. As of this writing, there have been no enforcement actions ï either settlements or actual court rulings ï construing the False Claims Act with respect to this specific fact pattern.

However, the quality reporting systems have given rise to some enforcement. For example, in U.S. ex rel. Sheldon v. Kettering Health Network[124], a *qui tam* relator brought suit against Kettering Health Network (KHN), claiming that KHN had falsely certified that it complied with the requirements of the HITECH Act pertaining to meaningful use of EHR software. The case did not survive a motion to dismiss, but the court dismissed because the relator had poorly pled the facts of the case and failed to state a specific violation, rather than because false attestation could not serve as grounds for FCA liability.[125] Notably, the court did

[124] 2015 WL 74950, (S.D.Ohio, 2015).

[125] The facts in the case found the relatorôs husband ï a KHN employee ï improperly accessing and disclosing the medical records of the relator and two other family members to a woman with whom the husband had begun an affair (herself also a KHN employee). According to the relator, KHN had, allegedly, failed to run certain internal tests to ensure the security and privacy of its networks. Therefore, the relator argued, KHNôs acceptance of MU incentive payments was improper, and must have been based on a false certification. The court described the fundamental problem of the case as follows, in rejecting the relatorôs request to amend her complaint a second time, ñIn sum, Plaintiff simply alleges that KHN violated the HITECH Act because one of its employeesé accessed her familyôs medical records. Accordingly, Plaintiff fails to state a claiml; and Relatorôs motion to amend is denied, as an amendment would be futile.ò Sheldon, at *5.

not state ï even in *dicta* ï that such a claim would be impossible with respect to whether an attestation of meaningful use of EHR software could, itself, form the basis for a false claims action based on a ñfalse certificationò theory.

The truly frightening scenario is one arising from a case like that of the former Chief Financial Officer for Shelby Regional Medical Center in Texas. On November 12, 2014, Joe White pled guilty to making false statements and was sentenced to twenty three months in federal prison, and was ordered to pay restitution amounting to over $4 million, all for having falsely attested to meaningful use of EHR software in 2012.[126] In fact, Shelby Regional Medical Center had relied primarily on paper records throughout 2012, and made little use of EHR software. White instructed the hospitalôs software vendor and employees to manually input data from paper records into the EHR software, in some cases months after the patient had been discharged and after the end of the reporting year.[127]

Shelby Regional Medical Center ï and White himself ï were lucky that the false statements in question were not made after 2015, and discovered after 2017. If they had been, then the prosecutors in the case could conceivably have brought false claims charges for: (1) the false attestation of meaningful use; (2) the retention of overpayments in the form of any incentive payments received by Shelby Regional Medical Center; and, (3) *every single claim paid in 2017 for which overpayments were not returned*, because each claim would have been paid 3% higher than it should have been.

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[126] ñFormer Shelby County Hospital CFR Sentenced in EHR Incentive Case,ò June 17, 2015, Department of Justice, U.S. Attorneyôs Office, Eastern District of Texas press release. http://www.justice.gov/usao-edtx/pr/former-shelby-county-hospital-cfo-sentenced-ehr-incentive-case.

[127] ñFormer Hospital CFO Charged with Health Care Fraud,ò February 6, 2014, Department of Justice, U.S. Attorneyôs Office, Eastern District of Texas press release. http://www.justice.gov/usao-edtx/pr/former-hospital-cfo-charged-health-care-fraud.

4.3 Future Problems with MIPS

Without published regulations, it is impossible to know the precise ways in which physicians will err under MIPS. However, we can make some reasonable guesses, in light of what we do know about how MIPS will function.

In some respects, MIPS will reduce potential FCA exposure by eliminating multiple different payments from different programs, and consolodating them into a single program. Under Medicareôs current quality reporting systems, errors in PQRS data will necessarily lead to errors in VPM data, since the two programs draw from the same submitted information. Errors in the data submitted by an EP can therefore lead to potential overpayments (and FCA liability) under both programs. This, in turn, could result in a single claim for payment being treated as a false claim twice: once with respect to the payment adjustment under PQRS, and once for adjustment under VPM.

Under MIPS, by contrast, all of the data will be reported to a single program with a single payment adjustment, and thus a single stream of false claims liability. Of course, the problems discussed above with regards to false claims liability under the current systems will still remain under MIPS. In spite of the consolidation of the existing quality reporting systems, physicians will still be reporting a broad range of information, and may have just as many ï or more ï ways to err as before, depending on the measures that will be used and the mechanisms for reporting. Improperly reported data can still result in the entire universe of an EPs claims being treated as false claims (if positive payment adjustments were applied that should not have been, or negative payment adjustments were not applied that should have been). In addition, the impact of negative payment adjustments under MIPS will be significant, with up to a -9.0% reduction in all Medicare payments for the lowest-ranked EPs.

CMS has anticipated its own potential to err in its application of payment adjustments under similar systems, which illustrates that CMS already recognizes this type of potential overpayment. In a discussion of the informal review process under VPM, CMS stated,

> ñTo minimize the impact on providers, we will classify a TIN as óaverage qualityô in the event that we determine that we have made an error in the calculation of the quality composite. However, we understand the point made by a few commenters about this policy. *It is possible that an 'average quality' rating for the CY 2015 payment adjustment period could potentially result in a higher or lower [VPM] payment adjustment amount for an individual TIN than if the quality composite were recalculated.*ò[128]

CMS further explained that it was developing operational infrastructure to allow it to recompute a TINôs quality composite and accept data similar to what it does under PQRS. The discussion that such recalculations could result in a higher VPM payment adjustment is worth noting. This language suggests that CMS recognizes that its internal errors might result in a mistaken payment (the retention of which could be treated as an overpayment, which itself could be treated as a false claim). However, the discussion in the preface makes no reference to false claims liability or voluntary repayment. In other words, in addressing issues relating to how professionals could challenge VPM determinations, CMS (1) recognized that it might make both negative *and positive* payment errors, and (2) did not even address the notion that an EP would have to return any overpayments, nor that the EP would potentially be exposed to FCA liability. It is, however, likely that CMS will attempt to minimize its risk of making improper positive payment adjustments; it is also highly unlikely that CMS will ñleave money on the tableò and implicitly waive FCA liability.

Thus, FCA liability will likely survive under MIPS. True, there will be a single universe of reported data and resulting payments, but the total dollar amount at stake could be much

[128] 79 Fed. Reg. 67960, November 13, 2014, emphasis added.

higher than what physicians have faced in the past, depending on where they fall on the winners-and-losers scale.

We already know that MIPS will not permit judicial review of basic issues.[129] The statute instructs the Secretary of Health and Human Services to establish a process by which EPs under MIPS may request an informal review to challenge the calculation of the MIPS adjustment factors as applied to the EP.[130] The precise method by which professionals may request informal review, however, has not been established at the time of this writing, and likely will not be established for several more years. If, however, history is any guide, CMS will likely operate the informal review process through a website (likely the same website through which EPs report their data), and will require EPs to submit a request for informal review by a specific deadline. That deadline will necessarily occur before the date on which payment adjustments will be applied, although it may be extended slightly to accommodate certain EPs.[131]

5. Conclusion

The nature of Medicare payment is changing. While fee-for-service payment is not likely to disappear in the forseeable future, MIPS represents a shift in holding professionals accountable both for the quality of care they provide, and the value of that care while they are paid fee-for-service. The individual quality reporting programs that have existed for several years have thus far failed to produce major changes in quality. However, with MIPS, CMS is more strongly incentivizing the provision of quality care at a reasonable price. It remains to be

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[129] See above, at ***PAGE FOR DISCUSSION OF MACRA TEXT AND PROHIBITIONS ON APPEALS.***

[130] 42 USC § 1395w-4(q)(13).

[131] For example, in 2015, CMS extended the deadline for requesting an informal review under the VPM. http://www.asoa.org/news/cms-extends-2016-value-based-payment-modifier-informal-review-deadline-december-16-2015. Similarly, CMS extended the deadline to request informal review under PQRS in that same year. http://csms.org/2015/10/30/cms-informal-review-deadline-extended-to-1123/.

seen how MIPS will actually play out in reaching this goal.

It is hardly rash speculation to say that physicians will continue to face headaches from the reporting mechanisms themselves, as well as difficulties in successfully participating in MIPS, just as they do under the current programs. These programs are complicated, and require considerable attention to detail to successfully report. Attorneys cannot be expected to understand every facet of the various quality reporting systems, from the specific measures and their associated requirements, to the method of calculating payments under programs like VPM and MIPS. However, a general understanding of these programs is essential in the development of compliance strategies for clients which can respond to problems when they arise. It is also likely that MIPS will change over time. The requirements laid out by MACRA form the overall framework for the program, but we can expect far more detailed regulations to follow. And, as always, it will be in these details that the devil will lurk.

Attorneys must likewise understand the risks their clients face in participating in these systems. Beyond the direct financial implications of failing to (a) secure an upward payment adjustment, (b) avoid a downward payment adjustment, or (c) receive an incentive payment, clients face significant risk with respect to False Claims Act liability. Clients may not always properly report their data, but attorneys must convey the potentially devastating impact of a false claims lawsuit that applies to an entire yearôs worth of Medicare billings, and then assist clients in coming to grips with how to approach compliance through efforts such as periodic self-audits.

For physicians and physician practices, programs such as PQRS, Meaningful Use, VPM, and MIPS are becoming the ñnew normal.ò There is no avoiding their impact, and that impact promises to grow over time. However, with the assistance of knowledgable legal counsel, our clients will be able to navigate this new landscape.