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By PollyBeth Hawk*

I. AN INTRODUCTION TO VALUE-DRIVEN REFORM

There are a multitude of healthcare reform forces converging on the United States' healthcare system, but arguably none as profoundly transformative as the government's value-driven healthcare agenda. The nation's healthcare stakeholders continue to grapple with reports and statistics detailing the delivery of inadequate care across provider settings compounded by spiraling healthcare costs and the looming threat of federal healthcare program insolvency.[1] One of the government's primary responses to this crisis is to alter the longstanding business model governing reimbursement of healthcare services provided to Medicare beneficiaries. To be sure, the Department of Health and Human Services ("HHS") is spearheading a fundamental transition of the health care payment and delivery system. Rather than continuing to reward the quantity of care delivered, the new system will reward the quality, efficiency, and cost-effectiveness of care. Under the current fee-for-service ("FFS") model, Centers for Medicare and Medicaid Services ("CMS") effectively pays healthcare providers to perform services without regard to quality and with no rewards for efficiency.[2] Furthermore, this model fails to effectively

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1. Health care costs today comprise one-seventh of the economy with spending totaling more than $2 trillion annually. By 2017, the nation is expected to spend roughly $4 trillion on health care, or twenty-one percent of gross domestic product. Medicare costs in particular are growing at unsustainable rates, with the Medicare Part A Hospital Insurance Trust Fund being projected to go bankrupt in 2019. Moreover, the Medicare chief actuary has observed that because of the current economic crisis, this date could be moved to as early as 2016. See, e.g., CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ROADMAP FOR IMPLEMENTING VALUE DRIVEN HEALTHCARE IN THE TRADITIONAL MEDICARE FEE-FOR-SERVICE PROGRAM 1 [hereinafter CMS ROADMAP], available at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/vbproadmap_oea_1-16_508.pdf.

2. See id.

create disincentives for overuse, under-use or misuse of care.[3] CMS does, however, recognize that these trends jeopardize the high quality care it expects to purchase and that the current payment model is not sustainable.[4]

Value-based purchasing ("VBP") is the centerpiece of the HHS mission to improve quality and achieve value for Medicare. In response to mandates set forth in the Patient Protection and Affordable Care Act of 2010 ("PPACA"),[5] CMS is implementing this innovative concept by incentivizing quality improvement through payment reform.[6] VBP allows CMS to reward providers for care delivered in a safe, effective and efficient manner.[7] CMS is positioning VBP programs to be instrumental in accomplishing its three-pronged strategy to shape its quality of care agenda for the Medicare program. This agenda is comprised of incentivizing quality through payment reforms, driving quality of care through public reporting, and enforcing quality of care through the False Claims Act ("FCA").[8] Thus, CMS aims to improve the quality of the health care it purchases by enticing providers to change their behaviors, and likewise holding them accountable for care delivered through a transparency campaign.

VBP programs serve as the reimbursement vehicle that ties government payment to how well providers adhere to evidence-based practice standards

3. See Inst. of Med. of the Nat'l Acads., Rewarding Provider Performance: Aligning Incentives in Medicare (Sept. 2006), available at http://www.iom.edu/~/media/Files/Report%20Files/2006/Rewarding-Provider-Performance-Aligning-Incentives-in-Medicare/RewardingProviderPerformanceAligningIncentivesinMedicare.pdf.

4. See, e.g., CMS ROADMAP, supra note 1; Daniel F. Shay, PQRS and its Penumbra, in HEALTH LAW HANDBOOK (Alice G. Gosfield, ed., 2012), available at http://www.gosfield.com/PDF/DFS_HLH2012_PQRS%20Penumbra.pdf.

5. See Patient Protection and Affordable Care Act, Pub. L. 111-148, §3001, 124 Stat. 119 (2010) (enacting VBP for inpatient hospital care for discharges occurring on or after October 1, 2012).

6. See CMS ROADMAP, supra note 1.

7. See id.

8. See, e.g., Janice A. Anderson & Susan M. Nedza, Quality of Care: Transforming Health Care Through Payment Reform, Public Reporting and Enforcement, Address at the 12th Annual HCCA Conference (Aug. 13-16, 2008), available at http://homecarenyc.org/upload/interactive/conference/morning/P8/JAA-PPT-HCCA.pdf (discussing the three-pronged quality strategy); see also Cheryl L. Wagonhurst, Pay for Performance Documentation and Coding, Address at the HCCA Quality of Care Compliance Conference (Oct. 11, 2009) (this material is no longer publicly available but was last accessed on Apr. 19, 2012 at http://www.hcca-qualitycare-conference.org/past/2009/502_Wagonhurst.pdf); Cheryl L. Wagonhurst et al., The Government's Three-Prong Approach to Quality of Care and Practical Strategies for Operational Improvement and Risk Reduction (Mar. 2009) (this material is no longer publicly available but was last accessed on Apr. 23, 2012 at http://hcca-info.org/AM/Template.cfm?Section=Home&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=8297) (also discussing the three-pronged quality strategy).

associated with clinical outcomes.[9] Simply, VBP, or "pay-for-performance" ("P4P"), is based on the principle that providers will achieve better outcomes if their reimbursements are linked directly to their performance and, consequently, health care will become more efficient and cost effective.[10] According to CMS, VBP will facilitate its transition "from a passive payer of services to an active purchaser of higher quality, affordable care."[11] Such an undertaking is historic and comprehensive in scope, as it will require a reorientation of healthcare regulations, policies and enforcement efforts, as well as moving from a focus on the volume of care to a focus on the value of care.

Although VBP is comprised of programs other than P4P, the two terms are often used synonymously in healthcare circles and will be used interchangeably herein.[12] CMS, however, frames the VBP concept as more complex, comprised of several payment policies or programs, all of which incentivize quality of care improvements by tying payment to satisfaction of quality targets.[13] These include the CMS "Never Events" Policy;[14]

9. KIMMEL, KATHLEEN C., ET AL., PAY FOR PERFORMANCE: AN ECONOMIC IMPERATIVE FOR CLINICAL INFORMATION SYSTEMS 1 (2005), available at http://www.himss.org/content/files/payforperformance.pdf.

10. By tying reimbursement directly to meeting performance criteria, VBP programs tackle the high cost of care issues that plague our national healthcare system. Where payment systems currently in place reward providers for the quantity of care delivered rather than the quality of care, providers are likewise not incentivized to coordinate care efforts to achieve the best possible outcomes for Medicare beneficiaries. VBP carries the potential to facilitate new collaborative approaches to care between and among providers and eliminate inefficiencies and redundancies, thereby improving care at a lower cost. See S. FIN. COMM., TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM: PROPOSALS TO IMPROVE PATIENT CARE AND REDUCE HEALTH CARE COSTS, at 1-3 (2009) [hereinafter PROPOSALS], available at http://www.apapracticecentral.org/advocacy/reform/finance-paper.pdf.

11. See CMS ROADMAP, supra note 1. CMS is the single largest payer of healthcare services in the United States with nearly ninety million beneficiaries relying on Medicare, Medicaid and State Children's Health Insurance Program (SCHIP). CMS has been tasked with the responsibility that these beneficiaries have access to high quality care. See id.

12. See, e.g., John Andrews, Quality is More Than a Simple Buzzword Healthcare, HEALTHCARE FINANCE NEWS, May 21, 2008, available at http://www.healthcarefinancenews.com/news/quality-more-simple-buzzword. But see, e.g., Robert A. Berenson, Senior Fellow, The Urban Inst., P4P and Transparency: Careful What You Wish For, Address at the AHQA Annual Meeting (Feb. 14, 2007), available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=26&ved=0CEUQFjAFOBQ&url=http%3A%2F%2Fwww.ahqa.org%2Fpub%2Fuploads%2F070214TransparencyPlenary_Berenson.ppt&ei=V6p7T7TBAuG80AGIiISdBg&usg=AFQjCNE_k6p40JyravmeqsXWLjjG6Bur3A&sig2=GC5Ydp3U5_S26g6YEm7BRw (noting that the Senate Finance Committee, the House Ways and Means Committee, and CMS have all adopted VBP in place of P4P but arguing that P4P is not synonymous with Value Based Purchasing as the VBP context is broader, generally encompassing programs focused on appropriate, high quality, cost-effective services).

13. See CMS ROADMAP, supra note 1.

14. On January 15, 2009, CMS issued three national coverage determinations to

Hospital-Acquired Conditions Policy;[15] Excess Readmissions Policy;[16] Pay-

establish uniform national policies that would prevent Medicare from paying for certain serious preventable errors in medical care. These included: wrong surgical or other invasive procedures performed on a patient; surgical or other invasive procedures performed on the wrong body part; and surgical or other invasive procedures performed on the wrong patient. See Am. Health Lawyers Ass'n, NCDs Barring Coverage of Three "Never Events" Issued by CMS, VII HEALTH LAWYERS WEEKLY ARCHIVE, Jan. 16, 2009, available at http://dev.ahla.susqtech.com/News/HLWArchive/Pages/2009/January%202009/January%2016%202009/CMSIssuesNCDsBarringCoverageOfThreeNeverEvents.aspx. For a full record of these NCDs, see http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R101NCD.pdf.

15. CMS selects those conditions that will no longer trigger higher payment when they are acquired during hospitalization. The conditions selected are characterized by being high volume, high cost and assigned to a higher paying MS-DRG when present as a secondary diagnosis. Further, hospital acquired conditions (HACs) are also those conditions which theoretically should have been reasonably prevented through the application of evidence-based guidelines. The policy was introduced in 2005 with the Deficit Reduction Act (at section 5001(c)) and has been implemented in progressive phases. Currently, CMS uses present-on-admission (POA) codes to adjust reimbursement depending on whether the patient acquired certain conditions during treatment. If a provider fails to use the POA code properly on a claim, CMS will reject the claim. If a particular diagnosis code's POA reports a HAC, CMS will not use that diagnosis to select a higher-paying DRG. Moreover, as mandated by PPACA and beginning in 2015, CMS will reduce overall payments by one percent to hospitals for an excessive number of HACs. There are currently twelve HAC categories. The purpose of the HAC regulations is to combat healthcare-associated complications in hospital settings and to protect federal healthcare funds from payment for services which should not have been necessary in the context of high quality care delivery. The HAC/POA policy is consistent with VBP goals in so far as it inextricably ties payment to quality for this particular category of care. See CTRS. FOR MEDICARE & MEDICAID SERVS., HOSPITAL ACQUIRED CONDITIONS (HAC) IN ACUTE INPATIENT PROSPECTIVE PAYMENT SYSTEM (IPPS) HOSPITALS 1 (2012), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/downloads/hacfactsheet.pdf; see also Hospital Acquired Conditions (Present on Admission Indicator), CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/index.html?redirect=/HospitalAcqCond. For a discussion of this policy, see generally Janice A. Anderson & Joseph T. Van Leer, Focusing on Quality: CMS Issues New Quality-Focused Rules, 14 COMPLIANCE TODAY 36, 40-41 (2012), available at http://www.polsinelli.com/files//upload/ComplianceTodayMarch2012.pdf;
SUSAN CHMIELESKI ET AL., ASHRM HEALTH REFORM SUMMARY OF KEY PROVISIONS 7 (2010); See CMS ROADMAP, supra note 1, at 10-11.

16. The Readmissions Reduction program (established by PPACA) began on October 1, 2012 and extends financial incentives to hospitals to reduce preventable readmission rates by reducing their IPPS payments for excessive readmissions. The program progressively adjusts payments down by one percent a year (beginning with a one percent base-operating DRG payment reduction) until reaching three percent in 2015. See Readmissions Reduction Program, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/
Readmissions-Reduction-Program.html. See Anderson & Van Leer, supra note 15; see also Cheryl Clark, 10 Things We Don't Know about Looming Readmission Penalties, HEALTHLEADERS MEDIA (March 29, 2012), http://www.healthleadersmedia.com/print/QUA-278331/10-Things-We-Dont-Know-About-Looming-Readmission-Penalties.

for-Reporting ("P4R"); and Pay-for-Performance.[17] Collectively, these programs represent the new reimbursement paradigm. P4P, however, is the cornerstone of VBP and the primary driver of Medicare's transformation to value-driven health care; as such, it is the principal subject of this paper's examination of VBP and associated fraud issues.

Moreover, although this paper focuses on acute care and critical access hospital VBP, it should be noted that other types of hospitals (e.g., long term care hospitals, inpatient rehabilitation hospitals, and inpatient psychiatric hospitals), as well as ambulatory surgery centers, skilled nursing facilities, hospice providers, medical homes and home health agencies, are all responding to quality data performance opportunities.[18] HHS is in various phases of program development for P4R, P4P and VBP programs across a variety of care settings. In particular, professional P4R and P4P programs are well-tested and in advanced stages of VBP development, with implementation of physician VBP set for 2015.[19] Certainly, the

17. See CMS ROADMAP, supra note 1, at 8. In future years, CMS will be implementing other provisions of PPACA that are designed to improve care while reducing costs. See, e.g., Administration Implements New Health Reform Provision to Improve Care Quality, Lower Cost, HEALTHCARE.GOV (Apr. 29, 2011), http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011a.html [hereinafter Administration Implements New Health Reform Provision].

18. Typically, these programs maintain similar goals and objectives and use similar quality improvement program formats, yet are tailored to quality priorities for the particular setting as reflected by the measures used to assess performance. See generally HARI Data Center, Understanding the Hospital Value-Based Purchasing (VBP) Program (Oct. 20, 2011), available at http://www.healthcare.ri.gov/documents/VBP%20final%20rule102011.pdf; CMS ROADMAP, supra note 1; Quality Initiatives – General Information, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/index.html?redirect=/QualityInitiativesGenInfo/; Samantha Burch & Andrew Ruskin, CMS' Role as Active Purchaser of Quality Services: Readmissions, HACs, and Value-Based Purchasing Programs, Address at the Institute on Medicare and Medicaid Payment Issues Conference (Mar. 31, 2011), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/MM11/burch_ruskin.pdf.

19. The Physician Quality Reporting System (PQRS) invites physicians and other eligible professionals to earn incentive payments by meeting quality targets for care they provide to Medicare beneficiaries. PQRS was initially the Physician Quality Reporting Initiative as established by Section 101 of the 2006 Tax Relief and Health Care Act. For 2012, individual or group practice-eligible professionals who met the criteria for satisfactory submission of PQRS quality measures data (over 200 available measures for 2012) for services furnished during the reporting period qualified to earn a PQRS incentive payment equal to 0.5% of the individual or group practice's total estimated Medicare Part B Physician Fee Schedule (PFS) allowed charges for covered professional services furnished during that same reporting period. Beginning in 2013, the PQRS will evolve into a hybrid payment model of bonuses and negative payment adjustments and ultimately, by 2015, PQRS becomes purely punitive. For the official CMS website governing physician reporting, see Physician Quality Reporting System, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

proliferation and advancements of P4R and P4P programs are noteworthy, although a discussion of all the various quality program profiles for various care settings is beyond the scope of this paper.

A. IOM's Emphasis on Quality Lays Foundation for VBP

The arrival of pay-for-performance in today's dynamic healthcare landscape follows more than a decade of quality-focused momentum. The Institute of Medicine ("IOM")[20] has played a particularly influential role in raising national awareness as to the wholly inadequate standard of care in the American healthcare system, as well as in setting forth compelling and practical solutions for meaningful quality improvements.[21] VBP's

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Instruments/PQRS/index.html?redirect=/pqrs/. Moreover, a physician-specific P4P program is also well underway. See generally Shay, supra note 4, at 4-6. CMS is preparing to track physician performance based on an expanded set of PQRS measures beginning January 1, 2013 for one year. Performance will then be evaluated based on a similar format and scoring methodology to the Hospital VBP, and performance will then be prospectively applied to future claims beginning in 2015. See id. at 19; see generally CTRS. FOR MEDICARE & MEDICAID SERVS., DEVELOPMENT OF A PLAN TO TRANSITION TO A MEDICARE VALUE-BASED PURCHASING PROGRAM FOR PHYSICIAN AND OTHER PROFESSIONAL SERVICES (2008), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/downloads//physicianvbp-plan-issues-paper.pdf. The physician VBP (known officially as the Physician Feedback/Value-Based Modifier Program) contemplates a payment modifier (up to five percent of the physician fee schedule at risk) contingent on performance by 2017. For more information, see Medicare FFS Physician Feedback/Value-Based Modifier Program, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html. For links to the rules and regulations governing the Physician Feedback/ Value Based Modifier Program, see Federal Regulations and Guidance, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/FederalRegulations.html.

20. Established in 1970, the IOM is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision-makers and the public. The stated purpose of this organization is to "help those in government and the private sector make informed health decisions by providing evidence upon which they can rely." See generally About the IOM, INST. OF MEDICINE OF THE NAT. ACADS., http://www.iom.edu/About-IOM.aspx.

21. After the release of their first major publication in 1996 that addressed the problems underlying quality of care deficiencies in the U.S. (America's Health in Transition: Protecting and Improving Quality), the IOM initiated ambitious and aggressive efforts to better understand America's quality of care issues and propose solutions to improve U.S. healthcare. The report defined the nature of the problem as one of overuse, misuse and underuse of health care services (Chassen et al, 1998). The IOM issued its landmark reports soon after, including To Err is Human: Building a Safer Health System (2000) and Crossing the Quality Chasm: A New Health System for the 21st Century (2001) proposing responses and solutions to the crisis it had called to America's attention. To Err is Human focused on the dire need to improve patient safety and quality of care in light of the extraordinary number of reported annual American deaths due to medical errors. The Quality Chasm report outlined priority quality issues and defined six aims (care should be safe, effective, patient-centered, timely, efficient and equitable) as well as ten rules for care delivery

insistence on higher quality care for Medicare beneficiaries traces its inspiration to the poignant messages broadcasted to America by IOM's landmark report To Err is Human. This publication raised awareness of a series of aggressive regulations and policies aimed at raising awareness of the importance of patient safety and laying the foundation for putting provider reimbursements at risk when safety and quality expectations are not met.[22]

In 2003, on the heels of the IOM's quality wake up call, Congress directed CMS to implement a robust quality reporting program to improve data collection on quality of care for hospitals paid under the Inpatient Prospective Payment System (IPPS). The Medicare Modernization Act (MMA) of 2003 established the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program[23] (now renamed Hospital Inpatient Quality Reporting program (IQR)).[24] IQR is a data reporting program that sets forth the conceptual and programmatic infrastructure for the current VBP program. This quality reporting initiative acted as the catalyst for the modern day quality movement, and set CMS on its way to becoming an "active purchaser of higher quality, affordable care."[25]

IQR, also known commonly as the hospital pay-for-reporting program, requires acute care hospitals to submit data on ten quality indicators in order to avoid negative reimbursement adjustments.[26] The quality measures used are based on scientific evidence and reflect guidelines, standards of care or practice parameters that collectively gauge how well an entity provides care to patients.[27] Initially, under RHQDAPU, a hospital's failure

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redesign. Generally, the IOM called for a radical transformation of the healthcare system "in order to close the chasm between what we know to be good quality care and what actually exists in practice." Some of the tenants of VBP can be traced to IOM recommendations in these reports, including their discussion of quality metrics that illustrate the breadth and depth of the quality chasm. See generally Announcement, Crossing the Quality Chasm: The IOM Health Care Quality Initiative, Institute of Medicine of the National Academies [hereinafter IOM Announcement], available at http://www.iom.edu/Global/News%20Announcements/Crossing-the-Quality-Chasm-The-IOM-Health-Care-Quality-Initiative.aspx.

22. See id.

23. Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, §501(b), 117 Stat. 2289 (2003); Social Security Act, 42 U.S.C. §1886(b)(3)(B)(vii) (2003) ("MMA"); Hospital Quality Initiative, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/index.html?redirect=/HospitalQualityInits/.

24. The name change became effective in 2010 with no changes to the program itself. See Quality Data Reporting, INFO. & QUALITY HEALTHCARE, http://www.iqh.org/index.php?option=com_content&view=article&id=24&Itemid=125.

25. See An Introduction to Value-Driven Reform, supra Section I.

26. MMA at § 501(b) at § 501(b).

27. See CMS ROADMAP, supra note 1, at 5-6.

to report on the requisite quality data resulted in a penalty of a 0.4 percentage point reduction in the Annual Payment Update (APU) for inpatient hospital services.[28] Then, the Deficit Reduction Act (DRA) of 2005 expanded the program adding additional quality measures and increasing the penalty for failure to report to two percentage points of Medicare's APU.[29] The 2012 IPPS final rule requires providers to successfully report on a total of fifty-five measures, and increases the number of measures to fifty-seven in fiscal year 2013.[30]

Effective for payments in calendar year 2009, CMS implemented a parallel quality program for outpatient hospital settings.[31] The Hospital Outpatient Quality Reporting (OQR) Program[32] measures how regularly a healthcare provider administers the outpatient treatment known to provide the best results for the most patients with a particular condition.[33] Like the IQR program, outpatient provider participants are required to satisfy program reporting and performance requirements (including data submission for fifteen measures in 2012 and twenty-three measures in

28. MMA at §501(b).

29. In 2006, Congress passed the Deficit Reduction Act of 2005 ("DRA"), Deficit Reduction Act of 2005, Pub. L. No. 109-171, §5001(b), 120 Stat. 4 (2006). See also PROPOSALS supra note 10, at 19-37. The Act expanded the measures list from ten to twenty-one quality measures starting in 2007. See CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE HOSPITAL VALUE-BASED PURCHASING PLAN DEVELOPMENT, ISSUES PAPER 29 (1st Sess., 2007), available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads//hospital_VBP_plan_issues_paper.pdf.

30. See FY 2012 IPPS Final Rule Home Page, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY-2012-IPPS-Final-Rule-Home-Page.html. The current Hospital IQR program maintains the same two percent downward adjustments to the hospital AMBU for failure to report on quality data applicable to the required quality targets. See Hospital Inpatient Quality Reporting (IQR) Program Overview, QUALITYNET, http://www.qualitynet.org/dcs/ContentServer?cid=1138115987129&pagename=QnetPublic%2FPage%2FQnetTier2&c=Page . For a discussion of current developments regarding the IQR, see Anderson & Van Leer, supra note 15, at 36. Additionally, CMS finalized the measures for Fiscal Year 2014 (fifty-five measures) and Fiscal Year 2015 (seventy-two measures). CMS continues to evaluate the usefulness of existing measures and will retire those that it considers "topped out," which means the measure no longer has significant room for improvement. See id.

31. Hospital Outpatient Quality Reporting (OQR) Program Overview, QUALITYNET, http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1191255879384.

32. The OQR is a P4R program mandated by the Tax Relief and Health Care Act of 2006 requiring "subsection (d) hospitals" to submit data on measures on the quality of care furnished by hospitals in outpatient settings." See Hospital Outpatient Quality Reporting Program, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalOutpatientQualityReportingProgram.html.

33. See id.

2013[34]), or face a two percentage point reduction in their APU under the Outpatient Prospective Payment System (OPPS).[35] Moreover, both the IQR and OQR programs[36] undertake the transparency obligations set forth in legislative mandates requiring CMS to publish each participating hospital's performance results on the publicly accessible Hospital Compare website.[37]

In value-based purchasing programs, quality measures[38] serve as tools that assist in quantifying healthcare processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with high-quality health care.[39] Quality measures convert medical information from patient records into a format (a rate or percentage) that allows the government and the quality program participants to evaluate performance.[40] Measures represent a care environment rooted in evidence-driven, systems-based care with provider-specific clinical protocols.[41] These quality measures shape P4P as a payment approach based on clinical, information-driven reform.[42]

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34. The twenty-three required data measures for 2013 include fourteen clinical performance measures; seven imaging efficiency measures; and two web-based structural measures. See Hospital Outpatient Quality Reporting (OQR) Program Overview, supra note 31. In 2014, CMS will add three more measures. See Janice A. Anderson & Joseph Van Leer, As Pay-for-Performance Programs Increase, Compliance Faces Complex New Challenges, 21 REPORT ON MEDICARE COMPLIANCE (2012), available at http://www.polsinelli.com//files//upload/ReportonMedicareCompliance-2.16.12.pdf.

35. See Hospital Outpatient Quality Reporting Program, supra note 321.

36. For an informative discussion of quality reporting, see Amy Thorpe & Adol Esquivel, Quality Reporting Alignment, Address at HIMSS Annual Conference and Exhibition (2012), available at http://69.59.162.218/HIMSS2012/Venetian%20Sands%20Expo%20Center/2.22.12_Wed/Marcello%204506/Wed_0945/96_Amy_Thorpe_Marcello%204506/96ThorpeFINALrevc.pdf.

37. What is Hospital Compare?, U.S. DEPT. OF HEALTH AND HUMAN SERVS., http://www.hospitalcompare.hhs.gov/. See IOM's Emphasis on Quality Lays Foundation for VBP, supra Section IA; see also infra notes 70-72.

38. Measures are comprised of a variety of elements, including adhering to recommended tasks for processes; adopting desired tools and/or infrastructure; improving or meeting benchmarks for measured outcomes; and/or cost savings or efficiency targets. See Janice Anderson, Advising Clients About Quality of Care Legal/ Compliance Risks, Michigan State Bar Health Section Teleconference (Dec. 9, 2008), available at http://www.michbar.org/health/pdfs/PayPerformance2.pdf.

39. See IOM Announcement, supra note 21 (identifying quality issue goals as effective, safe, efficient, patient-centered, equitable, and timely).

40. See CMS ROADMAP, supra note 1, at 6.

41. Robin Locke Nagele & Sidney S. Welch, The New Health Care: Do We Shop for Quality at Neimans or Filenes?, Address at American Health Lawyers Association Annual Meeting (June 27, 2011), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM11/nagele_welch_slides.pdf.

42. KIMMEL, supra note 9.

B. Hospital VBP Becomes Permanent Fixture in Healthcare Reimbursement

CMS laid a strong foundation for VBP through the widely successful demonstration projects and pilots that tested the tenets of VBP.[43] In 2005, the DRA initiated the transition from P4R to P4P with provisions mandating the Secretary of HHS to formulate and submit a plan for a hospital value-based purchasing program.[44] Subsequently, PPACA was the legislative catalyst making VBP official and positioning pay-for-performance to make significant strides in quality of care reform.[45] The Hospital VBP program is designed to promote better clinical outcomes for hospital patients as well as improve their experience of care during hospital stays.[46] This was a major step forward in a longstanding effort by CMS to forge a closer link between Medicare's payment systems and improvements in the quality and delivery of health care in the nation's hospitals.[47]

In April 2011, CMS issued the final rule establishing the Hospital VBP

43. See generally CMS ROADMAP, supra note 1; Jeff Flick, CMS Regional Administrator, CMS' Quality Initiatives: Past, Present, and Future (June 29, 2007), available at http://www.startechgroup.com/documents/2%20CMS%20Quality%20Initiatives%20Past%20Present%20Future%202007.pdf. The CMS/ Premier Healthcare Alliance Hospital Quality Incentive Demonstration (HQID) in particular lent much credibility to the VBP concept and offered proven support for its potential to effect real improvements in the quality of care in hospital settings. See also CMS/ Premier Hospital Quality Initiative Demonstration, PREMIER INC., https://www.premierinc.com/p4p/hqi/.

44. In 2006, Congress passed Public Law 109-171, the Deficit Reduction Act of 2005 (DRA), which under Section 5001(b) authorized CMS to develop a plan for VBP for Medicare hospital services commencing fiscal year 2009. On November 17, 2007, CMS responded to the DRA mandate by releasing a Report to Congress. CTRS. FOR MEDICARE & MEDICAID SERVS., REPORT TO CONGRESS: PLAN TO IMPLEMENT A MEDICARE HOSPITAL VALUE-BASED PURCHASING PROGRAM 1 (2007), available at http://www.racaudits.com/uploads/medicareVBP.pdf.

45. Section 3001(a)(1) of the Patient Protection and Affordable Care Act requires CMS to implement a Hospital VBP program that rewards hospitals for the quality of care they provide. Generally, VBP applies to "subsection (d) hospitals" which include most acute care hospitals under the IPPS but does not include psychiatric hospitals, rehabilitation hospitals, children's hospitals or long term care hospitals. Further, PPACA excludes VBP for hospitals that 1) do not participate in the Hospital IQR program; 2) have been cited for deficiencies that pose immediate jeopardy to the health and safety of patients during the performance period; 3) do not have a minimum number of applicable measures for the performance period; or 4) do not have a minimum of cases for the applicable measures for the performance period. For a discussion of PPACA's requirements, see Janice A. Anderson & Christopher Wilson, Reimbursement Changes Under Health Care Reform: Are You Prepared?, 13 Compliance Today, 30-31 (2011), available at http://www.polsinelli.com/files/Publication/a7b1ccbf-7779-4854-a3ec-5bbd4afd815d/Presentation/PublicationAttachment/58f11105-143a-40fb-b98e-bef260311745/AndersonWilson_090811.pdf.

46. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS ISSUES FINAL RULE FOR FIRST YEAR OF HOSPITAL VALUE-BASED PURCHASING PROGRAM (2011), available at http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3947.

47. See id.

program under the IPPS.[48] The Rule finalized a P4P program affecting payment for inpatient hospital stays in over 3,500 hospitals across the country.[49] A Hospital VBP plan was the next logical step to follow and build upon the success of the RHQDAPU/ IQR pay-for-reporting program.[50] Hospital Value-Based Purchasing incorporates all of the Hospital IQR quality measures and retains the reporting program's financial incentives for satisfying quality reporting criteria.[51] However, VBP takes quality improvement to a new level with a performance component that assesses achievements in the quality of care delivered by measuring actual improvements in clinical quality, patient centeredness and efficiency.[52] Under the program, Medicare will make incentive payments[53] to hospitals beginning in fiscal year 2013 based on how well they perform on each measure compared to their performance on the measure during a baseline performance period.[54]

The baseline and performance periods that will determine 2013 incentive payments have already been established. Specifically, for FY 2013 payment calculations, CMS will compare hospital performance during the performance period that commenced July 1, 2011 and ended March 31, 2012 against that same hospital's performance across the same quality measures for the baseline period that began July 1, 2009 and ended March 31, 2010.[55] CMS will score each hospital based on achievement and

48. Medicare Program; Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg., 26,490, 26,505 (May 6, 2011), amended by 76 Fed. Reg. 39,006 (July 5, 2011) (technical errors only) (codified at 42 C.F.R. pts. 422 & 480).

49. See id.; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

50. See CMS ROADMAP, supra note 1, at 11.

51. Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,491; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

52. Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,496; CMS ROADMAP, supra note 1, at 11.

53. Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,493; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46. PPACA requires CMS to fund the aggregate Hospital VBP incentive payments by reducing the base operating diagnosis-related group (DRG) payment amounts that determine the Medicare payment for each hospital inpatient discharge. The law sets the reduction at one percent in fiscal year 2013, rising to three percent by fiscal year 2017. The program is thereby funded by negative reimbursement adjustments, and as such, the Hospital VBP Program will not increase overall Medicare spending for inpatient stays in acute care hospitals. See id. As such, VBP scores determine how much of the withholding a hospital earns back; the program is a budget-neutral program and consequently produces winners and losers for each fiscal year. See Anderson & Van Leer, supra note 15, at 39-40.

54. Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,493; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

55. Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,493; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

improvement ranges for each applicable measure.[56] A hospital's score on each measure will be the higher of its achievement score[57] or its improvement score.[58] Finally, CMS will calculate a Total Performance Score for each hospital by combining the greater of its achievement or improvement points on each measure.[59]

For the fiscal year 2013 Hospital VBP program, CMS will measure hospital performance using two domains: the clinical process of care domain, which is comprised of twelve clinical processes of care measures,[60] and the patient experience of care domain, which is comprised of Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measures.[61] These domains encompass measures reflecting

56. See id.

57. For scoring on achievement, hospitals will be measured based on how much their current performance differs from all other hospitals' baseline period performance. Points will then be awarded based on the hospital's performance compared to the threshold and benchmark scores for all hospitals. Points will only be awarded for achievement if the hospital's performance during the performance period exceeds a minimum rate called the "threshold," which is defined by CMS as the fiftieth percentile of hospital scores during the baseline period. See Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,493-94; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 4646.

58. For scoring an improvement, hospitals will be assessed based on how much their current performance changes from their own baseline period performance. Points will then be awarded based on how much distance they cover between that baseline and the benchmark score. Points will only be awarded for improvement if the hospital's performance improved from their performance during the baseline period. See CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

59. The higher of a hospital's achievement or improvement scores are totaled for a score as to each measure domain; then each domain score is multiplied by the proposed domain weight and finally the weighted scores are added together. In fiscal year 2013, the clinical process of care domain will be weighted at seventy percent and the patient experience of care domain will be weighted at thirty percent. CMS will utilize a linear exchange function to calculate the percentage of value-based incentive payment earned by each hospital. Those hospitals that receive higher Total Performance Scores will receive higher incentive payments than those that receive lower Total Performance Scores. CMS notified each hospital of the estimated amount of its value-based incentive payment for fiscal year 2013 through its QualityNet account at least sixty days prior to October 1, 2012. CMS notified each hospital of the exact amount of its value-based incentive payment on November 1, 2012. Id.

60. The twelve measures of the clinical process include acute myocardial infarction (with two measure indicators); heart failure (with one measure indicator); pneumonia (with two measure indicators); healthcare-associated infections (with four measure indicators); and surgical care improvement (with three measure indicators). See Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,492; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 46.

61. HCAHPS patient measure indicators include communication with nurses; communication with doctors; responsiveness of hospital staff; pain management; communication about medicines; cleanliness and quietness of hospital environment; discharge information; and overall rating of hospital. See Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,497; CENTERS FOR MEDICARE & MEDICAID SERVICES, supra

outcomes and efficiency, emergency care, effective care coordination, patient safety, and structural elements.[62] These quality measures are used to assess and evaluate the quality of care that organizations and professionals provide to Medicare beneficiaries via the VBP performance assessment.[63] CMS has already announced new measures it will utilize in the Hospital VBP program for the fiscal year 2014 payment determination.[64]

C. VBP Building Blocks and Projected Path to Quality Care

In its "Roadmap for Implementing Value-Driven Healthcare in the Traditional Fee for Service Program,"[65] CMS illuminates the path of Value-Based Purchasing by setting forth a template outlining its purported progression. The template includes the following elements:

- Pay for Reporting
- Pay for Performance
- Measure Resource Use
- Pay for Value
- Align Financial Incentives
- Transparency/ Public Reporting

The first four elements comprise building blocks that facilitate an evolution toward more sophisticated versions of the basic "carrot" model that use payment incentives to facilitate quality of care improvements. In other words, P4R progresses toward the end goal of paying for value. As discussed, P4R paved the way for P4P programs. In turn, current P4P programs, still in their infancy, should effectively lay a foundation for

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note 4646.

62. CMS ROADMAP, supra note 1, at 27.

63. The development of quality measures for use in the VBP P4P program arise out of collaborations between CMS and other quality-focused organizations. In particular, in 2008, MIPPA directed the Secretary of HHS to identify and contract with a consensus-based entity to make recommendations regarding a national quality strategy including identification and endorsement of standardized measures. CMS and the National Quality Forum maintain an ongoing partnership to develop building blocks for quality improvement in the healthcare industry, particularly with identifying and endorsing quality measures for use P4P programs. See PROPOSALS, supra note 10, at 6. See also NQF in the Quality Landscape, NATIONAL QUALITY FORUM, http://www.qualityforum.org/Setting_Priorities/NQF_in_the_Quality_Landscape.aspx.

64. These 2014 measures include: mortality measures (with three associated measures); hospital acquired condition measures (comprised of eight associated measures); and AHRQ patient safety indicators, inpatient quality indicators, and composite measures (two associated measures). See Hospital Inpatient Value-Based Purchasing, 76 Fed. Reg. at 26,495. A new measure based on efficiency was also introduced addressing Medicare spending per beneficiary. Anderson & Wilson, supra note 455, at 31. CMS has noted that all forty-five measures specified under the Hospital IQR are candidate measures for use in VBP going forward. Id.

65. See CMS ROADMAP, supra note 1, at 4.

provider and physician readiness to undertake measurement of resource use, which uses the same basic VBP model tying payment to quality, yet where quality encompasses efficiency.[66] Ultimately, CMS envisions "the right care for every person every time."[67] As such, CMS' end-stage objective in the VBP program is to pay for value,[68] meaning to reimburse for superior clinical outcomes achieved with efficient use of resources on a cost-effective basis.[69]

The other two elements of the VBP template serve as foundational supports that move the reimbursement model toward quality and value. Alignment and Transparency play support roles in the development of Value-Based Purchasing as they are incorporated into provider operations and business structures. As discussed at length in Section 5, infra, CMS has emphasized the critical role of alignment of financial incentives between and among providers and physicians undertaking VBP programs. Regarding the final element of the VBP template, CMS utilizes the Hospital Compare tool to achieve its Transparency goals throughout its quality improvement mission. Hospital Compare is the web-based public reporting tool that debuted in 2005 as part of hospital P4R programs.[70] Providers

66. According to CMS, the goal to improve the quality of care in our nation not only involves better outcomes, but also a commitment to efficient care. CMS has a separate roadmap to achieve this. See CMS QUALITY IMPROVEMENT ROADMAP EXECUTIVE SUMMARY, https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/downloads//qualityroadmap.pdf. Resource use can be defined in many ways, but CMS efforts have focused primarily on metrics associated with episodes of care that is, a series of separate but clinically related services delivered over a defined time period. Resources used in episodes of care are defined as the program costs (including both the Medicare program and the beneficiary payment) as opposed to the costs that providers incur to deliver the services. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE RESOURCE USE MEASUREMENT PLAN 1-2, available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/ResourceUse_Roadmap_OEA_1-15_508.pdf.

67. See CENTERS FOR MEDICARE & MEDICAID SERVICES, supra note 29, at 1.

68. CMS describes the development of an efficiency model that informs providers about the value of their care as a parallel step to the ongoing development of quality measurement, payments for quality performance and resource utilization tools. CMS sets forth that, in order to achieve a mature P4P system, providers must be incentivized to promote efficiency in resource use while providing high quality care. CMS' policy to stop paying for reasonably preventable Hospital Acquired Conditions (HACs), as well as the evolution from P4R to P4P and the ongoing transition to a bundled end stage renal disease (ESRD) payment policy, already represent steps in the direction of true value. See CMS ROADMAP, supra note 1, at 26.

69. See CMS ROADMAP, supra note 1, at 26; Janice A. Anderson, Obstacles to Improving Quality of Care and How to Overcome Them, Address at the HCCA 13th Annual Compliance Institute Conference (Apr. 27, 2009), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2009/S408-1.pdf.

70. See Hospital Compare, U.S. DEPT. OF HEALTH AND HUMAN SERVS.,

continue to submit quality data through a secure portion of CMS' Quality.net website and the data is then used to populate Hospital Compare.[71] CMS posits that making transparent quality data and cost information available to consumers better equips them to make informed decisions about health care; better-informed consumers, in turn, have the consequential and desirable effect of encouraging and holding accountable providers for improving the quality of care provided at their institutions.[72]

II. THE RISK OF FRAUD IN VBP

HHS faces continued pressure from Congress to reduce improper payments and prevent fraud, waste and abuse in federal healthcare programs.[73] In addition to significant amendments to health care laws and regulations,[74] Congress has committed tremendous financial resources to enforcement agencies.[75] The 2010 reform bills[76] alone added $350 million

http://www.hospitalcompare.hhs.gov/.

71. See Id.; See also Hospital Compare, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalCompare.html (providing valid, credible and user-friendly information about the quality of care delivered in the nation's hospitals).

72. See CMS ROADMAP, supra note 1, at 6 (suggesting that accountability through reporting is achieved through both direct financial incentives (e.g., higher reimbursements) as well as indirect financial incentives (e.g., reputational)).

73. See generally U.S. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, OIG WORK PLAN FISCAL YEAR 2013, available at https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf (discussing the Congressional approach to this problem); see, e.g., Patient Protection and Affordable Care Act, infra note 74 (representing one of the single most significant examples of a legislative effort to curb fraud, waste and abuse in health care).

74. See generally Fraud Enforcement and Recovery Act, Pub. L. No. 111-121, 123 Stat. 1617 (2009); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 124 Stat. 1029 (2010) (Collectively, these acts of law strengthen the government's ability to fight healthcare fraud and abuse through criminal, civil and administrative provisions. In particular, the laws include provisions that remove or weaken historically available defenses, mandate compliance programs for most providers as well as regulatory changes that provide a variety of new investigative and oversight mechanisms).

75. Dept. of Justice, Office of Public Affairs, Health Care Fraud Prevention and Enforcement Efforts Result in Record-breaking Recoveries Totaling Nearly $4.1 Billion (Feb. 14, 2012), available at http://www.justice.gov/opa/pr/2012/February/12-ag-213.html; See also Sara Kay Wheeler, Addressing Overpayments and Refunds: Practical Strategies in Light of Healthcare Reform Requirements (2011), available at http://www.thefallinstitute.org/storage/2011_archive/fi_2011_overpayments_and_refunds.pdf (discussing federal funding of healthcare fraud and abuse enforcement and for examples of several settlement recoveries obtained by the government arising out of healthcare fraud prosecution).

76. See generally Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (2010); Health Care and Education Affordability Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (2010).

in prevention and enforcement funds through 2020.[77] The Office of Inspector General ("OIG") has reported astounding savings and recovery figures of $25.9 billion for fiscal year 2010[78] and $25 billion for fiscal year 2011.[79] The healthcare community is on notice that the generous funding allocated to the OIG and its partners is not just earmarked for pervasive, high-profile fraud, but also that investigative and enforcement activity will target improper practices of generally well-intentioned providers.[80]

Value Based Purchasing is one such area providers could find themselves vulnerable to fraud risks if they fail to implement adequate safeguards at their institutions. The reimbursement model for VBP programs in particular carries inherent risks of fraud because of the high stakes involved. That is, as VBP either rewards or penalizes providers depending on performance, and subsequent performance results are posted to public information sites, there is substantial financial and reputational value at stake if quality data does not meet the mark.[81] As such, with much to lose, providers may be tempted to provide false, inaccurate or otherwise unsupported data in order to protect their financial bottom line.

At the heart of new fraud risks facing VBP participants is simply the rapid multiplication and ready availability of data. Providers' clinical quality measures data is a significant and growing component of the wealth of health care data available to the government. There are many P4R and

77. These funds were awarded through the Healthcare Fraud & Abuse Control (HFAC) program. See David W. Hilgers & Sidney S. Welch, Physicians Post-PPACA: Not Going Bust at the Health Care Buffet, ABA HEALTH L. SECTION: THE HEALTH LAWYER Vol. 24, No. 3, Feb. 2012, at 4-8, available at http://www.americanbar.org/content/dam/aba/publishing/health_lawyer/health_mo_premium_hl_healthlawyer_v24_2403. See also U.S. Dept. of Health & Human Servs., The Affordable Care Act: New Tools to Fight Fraud, Strengthen Medicare and Protect Taxpayer Dollars, HEALTHCARE.GOV (Sept. 23, 2012, 1:38 PM), available at http://www.healthcare.gov/news/factsheets/2011/03/fraud03152011a.html.

78. Press Release, U.S. Department of Health and Human Services, Office of Inspector General News: OIG Reports $25.9 Billion in Savings and Expected Recoveries in FY 2010 (Dec. 15, 2012), available at http://oig.hhs.gov/publications/docs/press/2010/sar2010press.pdf.

79. DEPT. OF HEALTH & HUMAN SERVS., FISCAL YEAR 2013: JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES 7 (2012), available at https://oig.hhs.gov/publications/docs/budget/FY2013_HHSOIG_Congressional_Justification.pdf.

80. See generally Preventing Health Care Fraud: New Tools and Approaches to Combat Old Challenges: Hearing Before the S. Comm. on Finance, 112th Cong. 85-94 (2011), available at http://oig.hhs.gov/testimony/docs/2011/levinson_testimony_03022011.pdf. In his testimony to the Senate Finance Committee in March 2011, HHS Inspector General Daniel R. Levinson made clear the OIG's position that "healthcare fraud is not limited to career criminals and sham providers" alone, but rather includes large corporations and "institutions such as hospitals who have also committed fraud." See id at 86.

81. See, e.g., Wagonhurst, supra note 8.

P4P programs already underway or in various stages of development across provider setting types.[82] These initiatives, pilots and programs are moving decidedly toward mandatory and permanent integration into a Medicare reimbursement model, which will further expand the universe of data available to the OIG and its partners to identify, investigate and prosecute instances of fraud. VBP calls for the submission of vast scores of quality data used in the calculation of performance records for up to 3,500 hospitals starting in 2012.[83] Moreover, quality data is multiplying exponentially alongside a parallel data explosion as providers across the nation are adopting electronic health records ("EHR").[84] EHR provides the foundation for the universe of electronic health data comprised of patient records and billing and claim-based information, and is expanding constantly as providers are increasingly joining the ranks of EHR "meaningful use" participants.[85]

Not surprisingly, clinical quality data is increasingly a focal point of OIG interest, as evidenced by the OIG 2012 Work Plan.[86] The Plan announced investigative and legal agendas that include aggressive use of the FCA to ferret out and prosecute healthcare fraud.[87] Although the Plan includes

82. See An Introduction to Value-Driven Reform, supra Section I.

83. See HEALTHCARE.GOV, supra note 17.

84. Per CMS, an electronic health record (EHR) is "an electronic version of a patient's medical history that is maintained by the provider over time, and may include all of the key administrative clinical data relevant to that person's care under a particular provider, including demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports." See Electronic Health Records, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Medicare/E-Health/EHealthRecords/index.html?redirect=/EHealthRecords/. Further, "[t]he EHR automates access to information and has the potential to streamline the clinician's workflow. . .and support other care-related activities directly or indirectly through various interfaces, including evidence-based decision support, quality management, and outcomes reporting." See id.

85. See generally EHR Incentive Programs, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/.

86. DEPT. OF HEALTH AND HUMAN SERVS., OFFICE OF INSPECTOR GEN., 2012 WORK PLAN [hereinafter 2012 WORK PLAN], available at https://oig.hhs.gov/reports-and-publications/archives/workplan/2012/Work-Plan-2012.pdf.

87. See id. at Part IV-1-2, "Legal and Investigative Activities Related to Medicare and Medicaid." "When adequate evidence of violations exists, OIG staff members work closely with prosecutors from the Department of Justice (DOJ) to develop and pursue Federal false claims cases against individuals and entities that defraud the Government. Authorities relevant to this work come from the False Claims Amendments Act of 1986 and the Fraud Enforcement and Recovery Act of 2009. We assist DOJ prosecutors in litigation and settlement negotiations arising from these cases." OIG and its partners investigate individuals, facilities, or entities that, for example, bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes to inflate reimbursement amounts, and false claims submitted to obtain program funds. Id.

explicit reference to quality issues involving substandard or even worthless services,[88] false claims in connection with P4R and P4P did not fly under the OIG radar. In fact, for the first time the OIG announced in its annual plan that the agency will investigate the "reliability of Hospital-Reported Quality Measure Data."[89] OIG plans to "review hospitals' controls for ensuring the accuracy and validity of data related to quality of care that they submit to CMS for Medicare reimbursement."[90] So, CMS has announced the priority status of data integrity in VBP programs as well as their commitment to conduct audits and investigations to validate data submissions.

In the VBP context, quality data submitted to CMS amounts to an entirely new set of legal representations (separate and distinct from billing claims submissions) upon which false claims under the FCA could be based. VBP program participants will be held accountable for the integrity of this data which is increasingly subject to government oversight. Ultimately, the False Claims Act is the most powerful tool in the OIG arsenal to prosecute quality fraud.[91] Recalling CMS' three-pronged Quality Improvement Strategy,[92] VBP programs are well-positioned to have a significant impact on the first two prongs, including incentivizing quality through payment reforms and driving quality of care through public reporting; and, as discussed in this section, the FCA will fuel the enforcement element and third prong of CMS' vision to improve healthcare in the US.

III. GOVERNMENT STRATEGY TO IDENTIFY QUALITY DATA FRAUD

Hospitals are sharing infinitely more information as they take a big step beyond Medicare quality reporting and adjust to the reimbursement methodology linking payment to patient outcomes and satisfaction.[93] CMS,

88. The 2012 Work Plan states that the "OIG also examines quality-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which the programs may have been billed for medically unnecessary services, for services either not rendered or not rendered as prescribed, or for substandard care that is so deficient that it constitutes "worthless services." (emphasis added). See id. at Part IV-4.

89. See id. at Part I-IV.

90. See id.

91. See, e.g., Robert T. Rhoad, et al., A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement, 21 THE HEALTH LAWYER 14, 14 (2009), available at http://www.crowell.com/documents/New-False-Claims-Act-Amendments-And-Their-Impact-On-Health-Care-Fraud-Enforcement.pdf; Dave Nadler, President Signs Fraud Enforcement and Recovery Act of 2009, PROFESSIONAL SERVICES COUNCIL, Sept. 2009 at 30-32; see supra Anderson, note 38.

92. See An Introduction to Value-Driven Reform, infra Section I; see Anderson & Nedza, supra note 8.

93. See Nina Youngstrom, Medicare Value-Based Purchasing Opens A Large New Can

in conjunction with OIG and the Department of Justice (DOJ), enforce quality of care by using data mining and auditing techniques. These tools are capable of identifying instances of overpayment such as where VBP incentive payments were based on inaccurate scores or where penalties should have been assessed for failing to meet designated benchmarks.[94] With significant resources invested in the VBP program, it is not surprising that HHS has announced its intention to conduct audits of quality data in order to validate providers' data submissions that earn them precious Medicare dollars.[95]

In anticipation of audits and with the threat of the FCA looming large, the importance of adequate clinical documentation cannot be overstated. While documentation has always been crucial for providers billing through Medicare,[96] its importance now intensifies with VBP.[97] When CMS audits providers for VBP compliance, they are not conducting coding or medical necessity-type audits; rather, they are auditing from medical records.[98] As such, a provider who does not document a patient or other relevant patient information for a quality measure, thereby affecting its P4P score, may be flagged in an audit and consequently be subject to fraud liability.[99] Payment for services has always depended on accurate coding and

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of Compliance Worms, 20 Report on Medicare Compliance (2011), available at http://aishealth.com/archive/rmc032811-01.

94. See Anderson, supra note 69.

95. See generally id.; 2012 WORK PLAN, supra note 86, at 4-5; Robert E. Slavkin & Anne W. Hance, HCCA's Managed Care Compliance Conference (Feb. 2010), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Managed_Care_Compliance_Conference/2010/Sun/P3_Hance_Slavkin.pdf; Frank Sheeder, OIG has New, Intensive Hospital Compliance Initiative, HEALTH CARE ENFORCEMENT & COMPLIANCE MATTERS (Apr. 25, 2011), available at http://www.thecomplianceblog.com/2011/04/oig-has-new-intensive-hospital-compliance-initiative.html; Joe Watt & Curt Chase, Healthcare Reform: Compliance Implications of New Reimbursement and Integration Models, HCCA Regional Conference (Sept. 2011), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Regional_Conference/2011/Overland%20Park/ChaseWattcolor.pdf (recognizing CMS plans to audit quality data submissions).

96. See, e.g., MEDICARE PROGRAM INTEGRITY MANUAL (2012), available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads//pim83c03.pdf; James Carroll, Medicare Medical Necessity Reviews are Coming, And Soon, HEALTH LEADERS MEDIA (May 13, 2010), available at http://www.healthleadersmedia.com/content/LED-250947/CMS-Medical-Necessity-Reviews-Are-Coming-and-Soon.

97. See, e.g., George B. Breen & Betty B. Bibbins, Health Care Reform: Improving Healthcare Through Superior Clinical Documentation and Practicing in a Heightened Enforcement Climate, HCCA Physician Conference (Oct. 2011), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Clinical_Practice_Compliance_Conference/2011/Preconference/P4_Bibbins.pdf.

98. See Youngstrom, supra note 93.

99. See id.

adequately supporting documentation confirming the medical necessity condition of payment, and otherwise providing any information necessary to substantiate code selections.[100] Now, with VBP becoming a permanent fixture in America's hospitals, clinical documentation that supports quality data will likewise be used during auditing processes to validate VBP payments.[101]

As mentioned, data mining is an increasingly popular and highly effective auditing technique used to uncover fraud. This technological tool facilitates the ability to sort through masses of electronic information through database exploration, extract specific information in accordance with defined criteria, and then identify patterns of interest to its user.[102] The government recognizes the limitless value of amassing exponentially growing amounts of data and concurrently developing ways to exploit it pursuant to a variety of goals, including quality improvement.[103] For example, CMS has compiled an extensive computerized database of claims and services billed to Medicare by providers, which is then used by audit contractors to analyze coding and billing practices.[104] The information facilitates identification of unusual billing patterns and outliers which sets the auditing process in motion to retrieve any overpayments distributed by Medicare.[105] Moreover, CMS is aggressively developing a data warehouse strategy which includes, as its centerpiece, an Integrated Data Repository (IDR).[106] Of significance to VBP programs, the IDR will include clinical

100. See Wagonhurst, supra note 8.

101. See Wagonhurst, supra note 8; see also Breen & Bibbins, supra note 97.

102. See Data Mining: Before H. Subcomm. On Tech., Info. Pol'y, Intergov. Rel., and the Census, 108th Cong. (2003) (testimony of Mark A. Forman, Associate Director for E-Government and Information Technology, Office of Management and Budget), available at http://georgewbush-whitehouse.archives.gov/omb/legislative/testimony/forman032503.html. "Data mining combines techniques including statistical analysis, visualization, induction, and neural networks to explore large amounts of data and discover relationships and patterns that shed light on business problems." Greg Rogers & Ellen Joyner, Mining Your Data for Healthcare Quality Improvement, available at http://www.himss.org/content/files/Code%20184%20Rogers%20Mining%20Your%20Data%20for%20Healthcare%20Quality%20Improvement.pdf.

103. See, e.g., Harnessing Technology and Innovation to Cut Waste and Curb Fraud in Federal Health Programs: Before US S. Comm. on Homeland Sec. & Governmental Affairs, Subcomm. On Fed. Fin. Mgmt., Gov't Info, Fed. Servs., & Int'l Sec., (July 12, 2011) (testimony of Lewis Morris, Chief Counsel, Office of Inspector General) [hereinafter Lewis Morris Testimony], available at https://oig.hhs.gov/testimony/docs/2011/morris_testimony_07122011.pdf.

104. See Andrew B. Walcher & Jennifer Colagiovanni, Using Data Mining as a Component of Audit Defense, RAC MONITOR (Sept. 2, 2011), available at http://www.racmonitor.com/news/33-top-stories/645-using-data-mining-as-a-component-of-audit-defense.html.

105. See id.

106. The purpose of the IDR is to "ensure a consistent, reliable, secure, enterprise-wide

data as well as claims data.[107] IDR goals of providing greater information sharing with broader and easier access and enhanced data integration will serve to facilitate data mining capabilities pursuant to audits and drive accountability of providers submitting clinical data under VBP.[108]

The government employs several auditing programs that capitalize on the massive databases being developed as well as the capabilities of increasingly sophisticated data mining technologies. By way of example, with the installment of the permanent Recovery Audit Contractor program and the transition to Zone Program Integrity Contractors, [109] methods of preventing fraud and abuse have become progressively more organized and also highly reliant on data mining strategies.[110] Data mining is particularly effective in fraud control and prevention efforts that rely on intra- and inter-agency collaboration and for whom data sharing is critical to their mission.[111] The Health Care Fraud and Abuse Control (HCFAC)[112]

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view of data supporting CMS and its partners in more effective deliver[ing]. . .quality health care at lower cost to CMS' beneficiaries through state-of-the-art health informatics." See CMS Integrated Data Repository (IDR), CTRS. FOR MEDICARE & MEDICAID SERVS., available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.

107. See id. IDR is geared for use by multiple stakeholders, including beneficiaries, providers, and health plans. The IDR is designed to analyze data in place instead of relying on data extracts and can integrate claims from diverse sources in a meaningful way. Id.

108. See id.

109. Section 302 of Tax Relief and HealthCare Act of 2006 required a permanent RAC Program and required the Secretary of HHS to expand the program to all fifty states. CMS now has four RACs in place, each of whom is responsible for identifying overpayment and underpayment in their approximate one quarter of the country. See Recovery Audit Program, CTRS. FOR MEDICARE & MEDICAID SERVS., available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/index.html?redirect=/RAC/; CTRS. FOR MEDICARE & MEDICAID SERVS., IMPLEMENTATION OF RECOVERY AUDITING AT THE CENTERS FOR MEDICARE & MEDICAID SERVICES: FY 2010 REPORT TO CONGRESS AS REQUIRED BY SECTION 6411 OF AFFORDABLE CARE ACT 6 (2010), available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2010Report Congress.pdf.

110. See Walcher & Colagiovanni, supra note 104.

111. See Efforts to Combat Health Care Fraud and Abuse: Testimony Before the Subcomm. On Labor, Health and Human Servs., Educ., and Related Agencies of the Comm. on Appropriations, U.S. House of Representatives (Mar. 4, 2010) (testimony of Deputy Secretary William Corr), available at http://www.hhs.gov/asl/testify/2010/03/t20100304a.html (recognizing benefits of data sharing among agencies); see also U.S. DEP'T OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2010 51 (Jan. 2011), available at http://www.justice.gov/archive/dag/pubdoc/hcfacreport2010.pdf (describing government investment in data sharing techniques across agencies aimed at fraud detection and prevention).

112. Efforts to combat fraud were consolidated and strengthened under Public Law 104-191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Act

program utilizes a collaborative approach by coordinating Federal, State and local law enforcement activities as well as aligning the efforts of the OIG, its HHS partners and the DOJ.[113] By illustration, HCFAC manages the Health Enforcement Action Team (HEAT) program which uses Strike Forces that employ data analysis to pinpoint fraud hot spots by identifying suspicious billing patterns as they occur.[114]

Moreover, the OIG has publicly touted a new audit series it is conducting as part of a new hospital compliance initiative in which it uses data mining to identify instances of fraud and abuse within a pre-selected list of high-risk hospital billing practices.[115] Undoubtedly, healthcare data analysis is taking center stage in prevention and enforcement efforts. Collective efforts through data mining and data sharing strategically position CMS to make great strides in fraud enforcement and recovery efforts. For providers who choose not to prepare in earnest for the pay-for-performance transition, the use of data mining may uncover problematic patterns or practices that lead to audits, pre-payment reviews, payment suspensions and/or investigations, and ultimately even FCA liability.[116]

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established a comprehensive program to combat fraud committed against public (and private) health plans. HIPAA required the establishment of a national Health Care Fraud and Abuse Control Program under the joint direction of the Attorney General and the Secretary of the HHS acting through the HHS' OIG. See Healthcare Fraud and Abuse Control Program Report, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH AND HUMAN SERV., available at https://oig.hhs.gov/reports-and-publications/hcfac/index.asp.

113. See id. Describing OIG's collaborative approach, Inspector General Daniel Levinson testified as follows before the US Senate Committee on Finance: "To support this approach, OIG created a team of data experts composed of OIG special agents, statisticians, programmers, and auditors. Together, the team brings a wealth of experience in using sophisticated data analysis tools combined with criminal intelligence gathered directly from special agents in the field to identify more quickly ongoing health care fraud schemes and trends. To expand the coalition of data experts focused on this effort, OIG has garnered the support and participation of our law enforcement partners at DOJ and FBI." See also Preventing Health Care Fraud, supra note 80.

114. See RISK SOLUTIONS HEALTH CARE, THE RISE OF ORGANIZED CRIME IN HEALTH CARE: SOCIAL NETWORK ANALYTICS UNCOVER HIDDEN AND COMPLEX FRAUD SCHEMES 6 (2011), available at http://www.himss.org/content/files/LexisNexusRiseOrganized Crime.pdf; see also Lewis Morris Testimony supra note 103.

115. See Improper Medicare Payments: Hearing Before the Subcomm. On Gov't Org., Efficiency and Fin. Mgmt. of the H. Comm. on Oversight and Gov't Reform, 112th Cong. 3 (2011) (testimony of Daniel R. Levinson, Inspector Gen. of the U.S. Dep't of Health & Human Servs.), available at https://oig.hhs.gov/testimony/docs/2011/levinson_ testimony_07282011.pdf. Levinson explained that after identifying problem areas revealed through data mining, the OIG then selects claims to be tested and performs site visits where comprehensive reviews of billing and medical record documentation are executed. See id.

116. See Wagonhurst, supra note 8.

IV. THE FALSE CLAIMS ACT AND VALUE BASED PURCHASING

A. The Evolution of the FCA

The Civil False Claims Act prohibits the submission of false claims for payment where federal funds are involved.[117] Congress enacted the federal FCA in 1863 to respond to abuse of federally funded programs in the Civil War reconstruction era.[118] The Act witnessed a resurgence of popularity and strength as a result of amendments in 1986,[119] and by the early 1990s, the FCA had become the primary enforcement tool used by the federal government to combat fraud, waste, and abuse in federal healthcare programs.[120]

The FCA imposes civil liability on any person who knowingly submits, or causes to be submitted, a false or fraudulent claim to the Federal Government.[121] The "knowing" standard expressly set forth in this provision assures the statute of its broad reach as it encompasses acting in "deliberate ignorance" or "reckless disregard" of the truth as related to the fraudulent claim;[122] moreover, specific intent to defraud is not required.[123] In 2009, the Federal Enforcement Recovery Act[124] (FERA) amended the FCA to include a significant expansion of the FCA's liability provisions.[125]

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117. False Claims Act, 31 U.S.C. §§ 3729-3733 (2006).

118. See CHARLES DOYLE, QUI TAM: THE FALSE CLAIMS ACT AND RELATED FEDERAL STATUTES 5 (2009), available at http://www.fas.org/sgp/crs/misc/R40785.pdf.

119. The 1986 amendments lowered the standards for intent and burden of proof required to establish liability, enhanced whistleblower incentives, and increased damages and penalties. See, e.g., Rhoad, supra note 91, at 15.

120. See, e.g., id.; see also Dave Nadler, supra note 91. There is also a criminal False Claims Act, 18 U.S.C. § 287, with penalties including fines, imprisonment, or both. Moreover, there is a Criminal Health Care Fraud Statute, 18 U.S.C. § 1347, which prohibits knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program; or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. Proof of actual knowledge or specific intent to violate the law is not required. Penalties for violating the Criminal Health Care Fraud Statute may include fines, imprisonment, or both. It should also be noted that the OIG has authority under 42 U.S.C. § 1320 a-7, to impose exclusions from participation in all Federal health care programs on health care providers and suppliers who have been convicted of Medicare fraud. See generally CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE FRAUD & ABUSE: PREVENTION, DETECTION, AND REPORTING (2011), available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads//Fraud_and_Abuse.pdf.

121. 31 U.S.C. § 3729(a).

122. 31 U.S.C. § 3729(b).

123. See 31 U.S.C. § 3729(a)(1)(B).

124. Fraud Enforcement & Recovery Act of 2009, Pub. L. No. 111-21, 123 Stat. 1617.

125. See generally Rhoad, supra note 91, at 16-19 (discussing the impact of FERA on

FERA rendered many of the historical defenses available to defendants under the FCA unavailable or less effective.[126] Moreover, the consequences of being liable carries a risk that many providers simply cannot afford to undertake.[127] Under FERA, violations of the FCA are subject to Draconian penalties consisting of civil penalties of between $5,500 to $11,000 per violation and treble the amount of the government's damages, as well as attorneys' fees and costs to successful whistleblowers pursuant to qui tam provisions.[128]

With FERA, the FCA began to acquire, in the viewpoint of many, its reputation as a "recklessness" statute.[129] Backed with generous enforcement funding, equipped with far-reaching, government/relator-friendly provisions, and armed with the threat of devastating sanctions, the FCA has been applied broadly and aggressively across the healthcare industry and scored substantial judgments and settlements on behalf of the government.[130]

B. VBP is Ripe for OIG Focus Under FCA

One of the FCA's primary targets in exposing and punishing healthcare fraud is the fraudulent billing arena. In this context, false claim liability theories are mostly based on services submitted for reimbursement lacking medical necessity[131] and involve circumstances such as billing for services

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the FCA); KUTAK ROCK LLP, CLIENT ALERT—FALSE CLAIM ACT EXPANSION—THE FERA (2009), available at http://www.kutakrock.com/publications/government/FERA_060309.pdf.

126. See Rhoad, supra note 91, at 16.

127. See Brian C. Elmer & Andy Liu, "Because Of": FCA Damages and Penalties, CROWELL & MORING LLP 43, available at http://www.crowell.com/documents/Because-of_FCA-Damages-and-Penalties.pdf (describing the "remedial provisions of the False Claim Act" as "inflexible and severe").

128. 31 U.S.C. § 3729(a); see also Rhoad, supra note 91, at 15 (discussing FCA penalty provisions under 31 U.S.C. § 3729(a), as amended).

129. Rhoad, supra note 91, at 15 (observing that FERA perpetuated the FCA's reputation as "a 'recklessness' statute"); see Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 669-72 (2008) (opining that without the "intent" element, the FCA would be tantamount to an "all purpose fraud statute" whose reach is "boundless").

130. For a list of FCA Settlements from 2000 through February 2012, see Brian C. Elmer, False Claims Act Settlements 2000-2012, CROWELL & MORING LLP (Apr. 30, 2012), available at http://www.crowell.com/files/False-Claims-Act-FCA-Settlements-Crowell-Moring.pdf. For a list and discussion regarding settlements and judgments arising out of the FCA from January 2011 to July 2011, see 2011 Mid-Year False Claims Act Update, GIBSON DUNN (July 14, 2011), available at http://www.gibsondunn.com/publications/pages/2011Mid-YearFalseClaimsActUpdate.aspx.

131. See 42 U.S.C. § 1395y(a)(1)(A) (2010) ("no payment may be made under part A or part B for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."). On every Medicare reimbursement claim form, a physician must certify that the services rendered were medically necessary for the health of the

not rendered, "upcoding" of items for services, duplicate claims, unbundling, and excessive or unnecessary services, among others.[132]

Historically, quality fraud investigations and lawsuits have been generally based on three theories, to include express certification, implied certification and "worthless services."[133] Moreover, the OIG and federal prosecutors have developed momentum over the past decade targeting "quality fraud," or substandard quality of care, under the FCA.[134] Most recently, in its 2012 Work Plan, the OIG announced that its "Investigative Activities" will target quality of care issues that encompass both the worthless services and certification theories.[135]

VBP, however, transforms the quality fraud landscape. In the fraudulent billing context, reimbursement claims pursuant to hospital VBP are fundamentally different from IPPS billing claims. Whereas providers submit codes through the IPPS describing the items or services provided to Medicare beneficiaries in order to get paid for the item or service, VBP participants provide quality data in a standardized metrics format to demonstrate requisite clinical performance (outcomes, etc.) in order to earn a bonus or to avoid a penalty. This Section will explore how the traditional certification and worthless services legal theories are shaped by VBP's efforts to improve quality of hospital care, and discuss how the FCA will need to respond accordingly to ensure data integrity.

1. False Certification Theories

The false certification theories of liability assert that failure to comply with certain billing regulations amounts to submission of false claims when the provider has certified that the subject regulations were in fact met.[136] The "express certification theory" alleges that a provider falsely certified its claims for reimbursement by certifying compliance with the "medical

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beneficiary.

132. Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8,987, 8,990 (Feb. 23, 1998) (notice) (identifying eighteen of HHS's highest risk fraud billing targets).

133. Devin S. Schindler, Pay for Performance, Quality of Care and the Revitalization of the False Claims Act, 19 HEALTH MATRIX 387 (May 1, 2009), available at http://law.case.edu/studentLife/organizations/healthmatrix/files/Schindler%20PDF.pdf (discussing the leading quality fraud theories).

134. See id.

135. According to the 2012 Work Plan, the agency will examine "quality-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which the programs may have been billed for medically unnecessary services, for services either not rendered or not rendered as prescribed, or for substandard care that is so deficient that it constitutes 'worthless services.'" See 2012 WORK PLAN, supra note 86, at IV-4.

136. See Schindler, supra note 133, at 401.

necessity" condition of payment[137] when in fact the services provided allegedly did not meet the medical necessity condition upon which certification was based.[138] This theory of liability essentially attempts to equate medical necessity with medical quality.[139] Pursuant to the implied certification theory, however, a provider is allegedly falsely representing that the facility is in substantial compliance with all federal and state laws that impact its condition to participate in government payment programs.[140]

Both false certification theories were initially successful,[141] but the more recent trend has witnessed a decline in these theories' favorable outcomes.[142] The courts have generally rejected the notion that compliance with quality standards should be seen as a precondition to receiving payment.[143] Specifically, most courts are not willing to equate medical necessity with a quality guarantee under express certification.[144] Moreover, courts largely reject implied false certification theories in what is the typical absence of any underlying statute or regulation that expressly requires payment to be based on compliance therewith.[145]

In contrast, in the Value Based Purchasing context, quality data submission to earn a bonus or avoid a financial penalty would not implicate

137. Every claim submitted to CMS for reimbursement of a Medicare service includes a certification that the services for which reimbursement is sought were "medically indicated and necessary for the health of the patient." See CMS Form 1500, available at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads//CMS1500805.pdf; see also 42 U.S.C. § 1395y(a)(1)(A) (imposing the requirement that all services paid for by Medicare be "reasonable and necessary for the diagnosis or treatment of the illness or injury").

138. See Schindler, supra note 133, at 401.

139. See id.

140. See id.

141. See Schindler, supra note 133, at 402-03 (discussing case law upholding the false certification theories).

142. See John T. Brennan & Michael W. Paddock, Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards, J. HEALTH AND LIFE SCI. L. 37, 38-71 (2008) (discussing the shortcomings of false certification theories).

143. See id.

144. See Schindler, supra note 133, at 402-05. The landmark case of Mikes v. Straus viewed a defendant's certification of medical necessity as a legal representation that the procedure was in fact medically necessary, but the Court was unwilling to go further and evaluate the standard of care delivered with the procedure. Mikes v. Straus, 274 F. 3d 687 (2d Cir. 2001) (discussing the certification of medical necessity).

145. See Schindler, supra note 133, at 403-04. Critics of a far-reaching false certification theory argue that boundaries placed on the reach of the FCA by the courts are desirable from a policy perspective because to link the FCA to conditions of participation would empower the FCA with a federal malpractice arm, competing with or largely replacing the compliance oversight generally relegated through state or private credentialing entities, or otherwise compromising the regulatory discretion afforded CMS under the Social Security Act to respond to issues arising out of certification diligence. See id. at 389-93, 403-05.

the conditions (medical necessity) or regulations (impacting conditions of participation) upon which certification theories have been traditionally based in quality of care cases. This is so because claims for reimbursement in the traditional billing context are based on payments for services rendered and subject to reimbursement regulations, whereas VBP claims are based on exemplary performance data and are not subject to similar reimbursement regulations. Therefore, the FCA will not likely reach VBP reimbursement claims through traditional false certification theories.

2. Worthless Services Claims

When the government suspects that a provider has rendered substandard or deficient services to a Medicare beneficiary, it may pursue a FCA claim based on the "worthless services" theory.[146] Historically, this prosecutorial strategy has fared best for the government in the long-term care context, in light of the typical fact pattern involving allegations that nursing home residents received wholly inadequate care or no care at all.[147] However, the government could feasibly expand the application of this theory and charge other healthcare providers with similar allegations under compelling circumstances.[148] As such, the new reimbursement paradigm and rise of quality data submissions required by VBP and P4P programs will likely breathe new life into quality fraud investigations and prosecutions by offering the OIG new targets.

To illustrate, quality fraud investigations arising out of claims for services that were worthless or otherwise fraudulent may also signal the possibility that the quality data associated with the inaccurate or false documentation gave rise to inaccurate quality measure scores.

For example, if the government uncovered a pattern of billing for services that were never received by Medicare beneficiaries, but various

146. Schindler, supra note 133, at 396-97.

147. According to the OIG for HHS, between 1996 and 2003, more than twenty cases involving quality of care issues were settled against nursing homes based on alleged violations of the FCA. See Schindler, supra note 133, at 398 (2003) (statement of Dara Corrigon, Acting Principal Deputy Inspector General, U.S. Department of Health and Human Services), available at https://oig.hhs.gov/testimony/docs/2003/071703fin.pdf. Mr. Schindler suggests that the very nature of nursing home reimbursement places these facilities at a particular risk of being targeted for tort, civil enforcement and criminal cases under the various billing fraud statutes. See Schindler, supra note 133, at 399.

148. The use of worthless services to target substandard quality of care outside the nursing home context will depend largely on the distinction between "systematic and widespread malpractice" (laying a foundation for quality fraud) and "simple malpractice," which is not well-suited to the FCA but rather is historically handled by state malpractice laws. See Schindler, supra note 133, at 398-99. Certainly the government has validated worthless services applicability to the hospital setting by recognizing it as an investigative focus in its 2012 Work Plan. See 2012 WORK PLAN, supra note 86, at IV-4.

quality criteria or outcomes associated with the fictional service were recorded in the medical record, the quality data would be compromised and the scores submitted for VBP purposes would be false or fraudulent. Quality data would not be affected in all instances of billing fraud; it would ultimately depend on whether the service upon which the false claim was based was associated with the VBP program's required quality measures.

In summary, if the data to support quality measures for a VBP program was based on inappropriately or fraudulently billed services, then the underlying billing practices could jeopardize the reliability of the quality data and consequently expose the provider to additional liability under the FCA. Thus, the scope of an OIG investigation into a pattern of worthless services or other billing fraud would likely involve scrutiny of the quality data arising from the underlying fraud.

C. FCA Applications to VBP Arising out Link to Electronic Health Records

1. OIG's Interest in EHR has Implications for VBP

The scope of providers' vulnerability to fraud exposure cannot be fully gauged or appreciated without an understanding of the dynamic relationship between VBP and the EHR initiative. By way of background, the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA)[149] authorized Medicare and Medicaid incentive payments, and eventually penalties, to encourage physicians and hospitals to adopt and use EHRs.[150] Eligibility for these incentive payments requires that providers demonstrate "meaningful use" (MU)[151] of certified EHR technology[152] by

149. Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. § 300jj et seq. (2009); American Recovery and Reinvestment Act of 2009 (ARRA), 42 U.S.C. § 17901 et seq. (2009). ARRA designates approximately $27 billion of the $34 billion provided by the Act to modernize healthcare information systems and expand EHR adoption by 2014 by extending incentive payments to providers. EHR adoption and use is the subject of several of PPACA's provisions and Obama continues to urge the nation's providers to get on board with the new technology as evidenced by the President's 2012 budget, proposing a twenty-five percent increase in funding for the Office of the National Coordinator for Health Information Technology. See ERNST & YOUNG, CHAPTER 5: USING DATA TO GUIDE DECISIONS: INVESTING IN INFORMATION TECHNOLOGY, in NEW HORIZONS: THE ROAD LESS TRAVELED 58 (2011), available at http://www.ey.com/Publication/vwLUAssets/New_Horizons_2011_health_care_provider_report/$FILE/New_horizons_2011.pdf.

150. See generally EHR Incentive Program, supra note 85.

151. CMS defines "meaningful use" of a certified EHR as providers who show that they are "using certified EHR technology in ways that can be measured significantly in quality and in quantity." As defined by ARRA, the three specific components comprising MU

meeting standards of interoperability, clinical functionality and security as required by each of three successive "stages" of MU.[153] Starting in 2011, hospitals that met the definition of MU for their EHR became eligible for bonus payments.[154] Beginning in 2015, failing to meet MU will bring reductions in the annual IPPS market basket update.[155]

The EHR Incentive Program structure is remarkably similar to the VBP

include: 1) use of a certified EHR in a meaningful manner, such as e-prescribing; 2) use of certified EHR technology for electronic exchange of health information to improve quality of health care; and 3) use of certified EHR technology to submit clinical quality and other measures. See Meaningful Use, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html. To satisfy MU Stage 1, hospitals are required to meet fifteen core objectives (one of which includes an objective to submit fifteen quality measures for stroke, VTE and ED using eMeasures) as well as five out of ten menu objectives; to move to Stage 2 they must meet sixteen core objectives (including reporting on twenty-four quality measures) and two out of four menu objectives. See generally Bryn Hunt & Claire Turcotte, CMS Proposes Aggressive Stage 2 Meaningful Use, BRICKER & ECKLER (2012), available at http://www.bricker.com/publications-and-resources/publications-and-resources-details.aspx?publicationid=2390; Brenda Pawlak & Sandra Newman, A Closer Look at the Stage 2 Meaningful Use Proposed Rule, IHEALTHBEAT (2012), available at http://www.ihealthbeat.org/features/2012/a-closer-look-at-the-stage-2-meaningful-use-proposed-rule.aspx#ixzzlpCH36ggZ (discussing MU Stage requirements).

152. A certified EHR means technology consists of electronic records of health-related information on an individual that includes patient demographic and clinical information (e.g., medical history and problem lists) with functionality for clinical decision support, physician order entry, and quality information reporting. The technology also needs to exchange and integrate electronic health information with and from other sources. See Amy S. Leopard & Paul L. Weygandt, Compliance Clinical Documentation in the Era of Health Reform: ACOs, MACs/ RACs and Facts, AM. HEALTH LAWYERS ASSOCIATION 5 (2011), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/Fraud11/papers/105_leopard_weygandt.pdf.

153. See ERNST & YOUNG, supra note 149, at 56-60 (discussing CMS requirements for three stages of EHR adoption).

154. For hospitals subject to the IPPS, the amount of the incentive payment depends on when the hospital first demonstrates MU of a certified EHR, the size of the facility and the hospital's Medicare share. See PROPOSALS, supra note 10, at 20. Critical Access Hospitals are categorized separately from the program's "Eligible Hospitals" and, as such, are subject to different rules and criteria. See id. See also Kathie McDonald-McClure & Kristen Holt, Address at HCCA Mid Central Regional Annual Conference: Electronic Health Records: Updates on Registration, Meaningful Use, and Incentive Programs (Nov. 4, 2011), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Regional_Conference/2011/Louisville/Holtcolor.pdf (discussing MU and, in particular, incentive payment calculation guidelines). Hospitals who remain meaningful users from 2011-2013 will receive full four years of payments. CMS reported that it paid approximately $20 billion in incentive payments for providers meeting MU requirements in 2011. The Health Information Technology for Economic and Clinical Health Act provides $36 billion in incentives for adopting EHRs over the course of the program. Id.

155. See CMS Medicare and Medicaid EHR Incentive Programs, CENTERS FOR MEDICARE & MEDICAID SERVICES, available at https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EHRIncentProgtimeline508V1.pdf (providing a timeline of the EHR Incentive Program milestones).

model, and furthermore the government has strategically linked the two to further advance the programs' individual goals. Consequently, how quickly a hospital achieves MU of its EHR under HITECH standards should likewise reflect how meaningfully those providers are participating in hospital VBP programs as well.[156] This is because the EHR program's MU requirements include demonstrating that the user can submit clinical quality measures (CQMs) that similarly satisfy certain VBP programs. In Stage 2 of EHR MU, the provider must demonstrate calculation of performance scores based on numerator, denominator and exclusions data in the format required by CMS.[157] While providers can currently submit clinical data to CMS through other VBP program formats, the VBP and EHR quality measures and submission formats are increasingly aligning such that eventually EHR should exclusively designate the CQM criteria and reporting format for VBP programs.[158]

As this VBP/ EHR alignment progresses, providers should remain mindful of the respective fraud issues associated with each. In its 2012 Work Plan, the OIG announced a new focus on "Fraud Vulnerabilities Presented by Electronic Health Records."[159] OIG's interest in fraudulent activity in EHR use has serious implications for the VBP programs. Specifically, HHS stated in the Work Plan that it will "review Medicare incentive payments to physicians and hospitals for EHR adoption and evaluate the effectiveness of CMS safeguards to prevent erroneous payments."[160] As discussed, the government strongly encourages the use of EHR through financial incentives, and essentially ensures its adoption by

156. See Clinical Quality Measures (CQMs), CENTERS FOR MEDICARE & MEDICAID SERVICES, available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html (discussing CQM reporting requirements under the EHR Incentive Program). CMS emphasizes that EHR is a critical component of both the data strategy of value based purchasing as well as for the incentive payment offered through it. See CMS ROADMAP, supra note 1, at 6.

157. Stage 2, CTRS. FOR MEDICARE & MEDICAID SERVS., available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html.

158. CMS is moving toward a requirement that quality data for its VBP programs be submitted directly through a provider's EHR; likewise, Stage 2 MU Proposed Rule revises the definition of a "meaningful EHR user" to one that incorporates the requirement to submit clinical quality measures. See Pawlak & Newman, supra note 151.

159. See 2012 WORK PLAN, supra note 86, at Part VII.

160. Id. at Appendix B. The OIG agenda encompasses review of 2011 incentive payments. During 2011, providers would have submitted VBP program quality data through an attestation method but not directly through an EHR since providers were not yet operating in EHR MU Stage 2. However, as discussed herein, providers began reporting quality data to CMS electronically in 2012 and will additionally be required to submit CQMs electronically once operating in MU Stage 2. OIG's agenda signals a risk of fraud exposure for providers undertaking VBP. Id.

threat of financial penalties. Meanwhile, CMS is extending compelling rewards in exchange for providers' exceptional performance data.[161] Indeed, as providers' VBP programs become more sophisticated, providers will be required to submit all of their quality data through an EHR system. As such, the OIG's focus on fraud vulnerabilities in EHR use will necessarily involve an examination of the integrity of the quality measures data submission processes. Hospitals are wise to jump on board with EHR implementation and VBP program participation, especially since meaningful use of EHR is critical to the long-term success of VBP.

Currently, the required quality measures for the Hospital VBP program do not perfectly align with the CQMs required under the EHR Incentive Program. That is, while there is some overlap among the measures required of the various P4P programs and the EHR Incentive Program, there are also some variations across the programs.[162] The government recognizes that these disparities can be problematic and burdensome. Using the same specifications for similar MU and VBP measures would reduce confusion, reduce the costs of developing measures, and potentially address the limitations of CMS data collection methods.[163] The issue is ultimately addressed by the Stage 2 Proposed Rule, which aligns Hospital VBP measures with the EHR Incentive Program CQMs, as well as with other existing quality programs.[164]

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161. See Hospital VBP Becomes Permanent Fixture in Healthcare Reimbursement, supra Section IB.

162. Specifically, some of the clinical quality measures in the incentive program for the MU of certified EHRs do not overlap or align with the Hospital IQR program and the VBP Program. CMS has announced it is "actively planning to synchronize the various reporting programs in order to ensure harmony among measures across various settings." See Mary Mosquera, For Hospitals, Value-based Purchasing Starts With Meaningful Use, GOVHEALTHIT.COM (May 3, 2011), available at http://www.govhealthit.com/news/hospitals-value-based-purchasing-starts-meaningful-use. CMS will work with the Office of the National Coordinator for Health IT on operational issues involved when aligning VBP and MU, including harmonizing the specifications of overlapping measures and considering developing new policies to protect patient privacy when accessing electronic data. See id.

163. See Shay, supra note 4, at 1.

164. See MEDICARE AND MEDICAID EHR INCENTIVE PROGRAM STAGE 2 PROPOSED RULE (2012), available at https://www.federalregister.gov/articles/2012/03/07/2012-4443/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-2. Beginning in 2014, the twenty-four CQMs on which hospitals must report under the EHR Incentive Program (Stage 2 MU) will match the Hospital VBP Program, the Joint Commission quality measures, the Medicare Hospital IQR Program and the National Quality Strategy. See Pawlak & Newman, supra note 151. For an in-depth discussion of quality alignment issues, see Amy Thorpe & Adol Esquivel, Quality Reporting Alignment 12th Annual Conference and Exhibition, available at http://69.59.162.218/HIMSS2012/Venetian%20Sands%20Expo%20Center/2.22.12_Wed/Marcello%204506/Wed_0945/96_Amy_Thorpe_Marcello%204506/96ThorpeFINALrevc.pdf.

2. Fraud Issues in Provider Attestations of VBP Data

Currently, CMS accepts two methods of quality data reporting for Hospital VBP. In 2011, CMS only accepted quality data for Hospital VBP through an attestation method.[165] In 2012, providers could have continued to use CMS' attestation tool, or those who had met the requisite level of EHR sophistication could have elected to submit quality data electronically through the EHR Electronic Reporting Pilot.[166] This section explores how and why providers choosing to use CMS' attestation tool risk additional fraud vulnerability compared to providers choosing to participate in the electronic reporting program. While all providers are subject to false claims liability under the FCA for submitting false or inaccurate performance data upon which reimbursements are based, the attesting providers risk liability under the FCA pursuant to a separate and additional false claims basis for the false attestation itself.[167]

Providers working in Stage 1 of MU are not required to report electronically; rather, these providers use attestation to submit their quality data.[168] In order to submit quality data by attestation, a hospital must have successfully registered for the Medicare EHR Incentive Program and have met the MU criteria using certified EHR technology.[169] Although their EHR generates the requisite quality data, the individual provider independently enters that data into a web-based system.[170] It is the act of

165. See Registration & Attestation, CENTERS FOR MEDICARE & MEDICAID SERVICES, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/RegistrationandAttestation.html (providing more information regarding the attestation method for submitting quality data). This is the same tool used for attestation in connection with the EHR Incentive Program. Id.

166. Eligible hospitals and Critical Access Hospitals (as defined under the EHR Incentive Program) may report through the Hospital IQR in order to participate in the electronic reporting option to submit their quality data to be eligible for an incentive payment. Information regarding this process can be found at Electronic Health Record (EHR) Incentive 2012 Reporting Pilot Program Overview, QUALITYNET, http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1228771190900 [hereinafter Reporting Pilot Program Overview].

167. See Schindler, supra note 133, at 394 (discussing false certification claims as separate and distinct from underlying billing fraud claims); see also Max Kennerly, Electronic Health Records Fraud, The New Frontier In False Claims, LITIGATION AND TRIAL BLOG (May 19, 2011), available at http://www.litigationandtrial.com/2011/05/articles/attorney/whistleblower/electronic-health-records-fraud-the-new-frontier-in-false-claims/. In the legal context, an attestation is a confirmation that something is true, genuine, or authentic. See Attestation: Definition, LEGAL INFORMATION INSTITUTE (Aug. 19, 2010), available at http://www.law.cornell.edu/wex/attestation.

168. See Registration & Attestation, supra note 165.

169. See id.

170. See id. CMS explains that "In the Registration and Attestation System, providers will fill in numerators and denominators for the meaningful use objectives and clinical quality measures, indicate if they qualify for exclusions to specific objectives, and legally

loading quality data into a separate IT application (such as where a nurse abstracts information from the EHR and enters it into a government-sponsored standalone quality reporting system) that gives rise to fraud risks. If the provider is using the attestation method and entering data into the CMS web-based system, there is potential FCA liability if the quality data entered by the provider does not exactly match the quality data scores generated by the certified EHR. Any manipulation of the original data upon which calculations are based, particularly where scores are made more favorable for receipt of an incentive payment or to avoid financial penalties, amounts to a false claim.[171] With financial rewards at stake, providers could be tempted to manipulate and/or falsify the data upon which performance will be evaluated.[172]

Thus, the attestation method is not simply a formality, but rather carries legal import similar to courts recognizing false certification claims. Recalling the discussion in Section IVB, the government has pursued false certification claims against providers under the FCA alleging a provider incurs liability for falsely certifying compliance with regulations with which the provider was allegedly not compliant. In these instances, the government's position has been to recognize false certification as a claim giving rise to liability separate and distinct from underlying billing fraud.[173]

By 2012, however, hospitals were extended the option to begin reporting electronically through the EHR Incentive Program 2012 Reporting Pilot ("Pilot"). The Pilot is a voluntary, electronic reporting option that allows meaningful users to satisfy the CQM objective for the EHR Incentive Program.[174] In order to report CQMs from an EHR, the EHR Incentive Program requires use of electronic specifications derived from certified

attest that they have successfully demonstrated meaningful use. Once providers have completed a successful online submission through the Attestation System, they will qualify for a Medicare EHR incentive payment" (emphasis added). Id.

171. See Steven T. Miller & Alastair MacGregor, Ethical Dimensions of Meaningful Use Requirements for Electronic Health Records, 13 AM. MED. ASS'N J. OF ETHICS 176, 176-80 (2011), available at http://virtualmentor.ama-assn.org/2011/03/pdf/vm-1103.pdf (recognizing that, though it would be possible to falsify paper reporting, "health care personnel must avoid any inclination to game the rules or view attestation as a means to a financial end. . . [n]ot only would such falsification violate the moral imperative against lying, [it would also open up] the organization and its senior officers to audits, fraud charges, and reclamation of funds under the False Claims ActFalse"). Id.

172. See Jim Tate, First the EHR Incentives. . .then the Audits? HITECH ANSWERS (June 2, 2011), available at http://www.hitechanswers.net/ehr-incentive-audits/ (warning that while providers may be tempted to enter attestation numbers or measures statements that are not supported by adequate documentation, this is not advisable as it amounts to fraud and may be uncovered during CMS attestation audits).

173. See VBP is Ripe for OIG Focus Under FCA, supra Section IVB.

174. Although voluntary, Pilot Program participation is "highly encouraged," per CMS. See Reporting Pilot Program Overview, supra note 166.

EHRs.[175] The Pilot tests the submission of quality measures data from EHR for hospitals and professionals.[176] Participating hospitals will report on fifteen CQMs originating from the RHQDAPU/ IQR measures list.[177]

The electronic reporting method should not give rise to false claims liability separate and distinct from other quality fraud issues associated with the integrity of the data submitted. While a provider is always within the FCA's ambit regardless of the reporting method arising out of the submission of false or inaccurate quality data for federal reimbursement, there is, however, no opportunity for data manipulation at the point of data submission to CMS with electronic reporting (and therefore, no liability associated with the EHR's automated data submission to CMS through electronic reporting). The certified EHR accomplishes both the task of performance calculations as well as the task of submission to CMS, which ensures that the data ultimately submitted for payment is necessarily identical to the data scored by the EHR. Consequently, with electronic reporting, there is no role for a human to enter (and falsify) certified EHR data to CMS; as such, the only reporting method likely giving rise to separate and distinct false claims liability for the submission of quality data is through the CMS attestation tool.[178] So, as providers move toward

175. Required specifications would include the data elements, logic and definitions for that measure in a format that can be captured or stored in the EHR so that the data can be sent or shared electronically with other entities in a structured, standardized format. Electronic Specifications for Clinical Quality Measures, CTRS. FOR MEDICARE & MEDICAID SERVS., available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Electronic_Reporting_Spec.html; see also CTRS. FOR MEDICARE & MEDICAID SERVS., GUIDE FOR READING ELIGIBLE PROFESSIONAL (EP) AND ELIGIBLE HOSPITAL (EH) EMEASURES (Oct. 2012), available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Guide_Reading_EP_Hospital_eCQMs.pdf.

176. Eligible professionals will report CQMs through the PQRS and eligible hospitals will report CQMs through the Hospital IQR program. See IOM's Emphasis on Quality Lays Foundation for VBP, supra Section IA.

177. See CMS ROADMAP, supra note 1, at 1. The fifteen CQMs required for hospital reporting fall into three major categories: 1) Emergency Department throughput processes; 2) Stroke patient management; and 3) Venous thromboembolism patient management. Medicare and Medicaid Programs: Electronic Health Record Incentive Programs: Final Rule, 75 Fed. Reg. 44,314, 44,418 (Jul. 28, 2010) (setting forth the CQMs in Table 10). No performance criteria are associated with payments based on 2012 reporting; reimbursements will be tied to performance based on discharges on or after October 1, 2012 (fiscal year 2013). Clinical Quality Measures (CQMs), CENTERS FOR MEDICARE & MEDICAID SERVICES , available at http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html#Other. For a discussion of CMS' goals of achieving widespread provider MU in 2012, see Marilyn Tavenner & Farzad Mostashari, 2012: the Year of Meaningful Use, THE CMS BLOG (Mar. 23, 2012), available at http://blog.cms.gov/2012/03/23/2012-the-year-of-meaningful-use/.

178. See Miller and MacGregor, supra note 171. See also Kathie McDonald-McClure & Kristen Holt, Electronic Health Records: Updates on Registration, Meaningful Use and

industry-wide EHR integration, we should expect to see less FCA liability based on false attestations arising out of the data submission process associated with VBP.

The government has made clear its intention to audit providers to confirm that incentive payments (both for the EHR Incentive Program and P4P) are well supported.[179] CMS has confirmed that it will be conducting audits for attestations taking place in 2011, prior to the use of an electronic reporting method.[180] The auditing process will focus on the EHR report comprised of quality data information as well as supporting payment calculations data and supporting clinical documentation.[181]

D. FCA Amendments under FERA Introduce New Fraud Vulnerabilities

The 2009 FERA amendments to the FCA effectively transformed the fraud playing field.[182] In particular, FERA strengthened two longstanding

Incentive Payments, Address at the HCCA's Mid Central Regional Conference 2011 (Nov. 4, 2011), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Regional_Conference/2011/Louisville/Holthandout.pdf (advising accuracy in attestation is critical in light of CMS reviews of attestation veracity); see also Tate supra note 172.

179. See, e.g., Grant Huang, CMS: Keep EHR Attestation Records for 6 Years in Some Form, DECISIONHEALTH (Sept. 12, 2011), available at http://pbn.decisionhealth.com/Blogs/Detail.aspx?id=200113 (discussing CMS announcement that providers should save supporting documentation for attestation for at least six years and to expect audits); See CMS is Developing an Audit Strategy: Shouldn't You?, EVERYTHING HITECH (Dec. 5, 2011), available at http://www.everythinghitech.com/everything-hitech/2011/12/cms-is-developing-an-audit-strategy-shouldnt-you-.html; Jim Tate, Meaningful Use Attestation: A Word to the Wise on Audits, HITECH ANSWERS (Dec. 13, 2011), available at http://www.hitechanswers.net/meaningful-use-attestation-process-and-ehr-incentive-audits/.

180. See Huang, supra note 179. Experts have suggested the most likely approach to validating incentive payments will involve random or sampling audits and other verification methods. Id.

181. See Youngstrom, supra note 93; see also Tate, supra note 179. To prepare for audits, CMS has advised providers who are attesting to receive an HER incentive payment for either Medicare or Medicaid EHR Incentive Programs "should retain all relevant supporting documentation in either paper or electronic format used in the completion of the Attestation Module responses. Documentation to support payment calculations should continue to follow the current documentation retention processes." See Id. For further information regarding registration and attestation for a Medicaid EHR Incentive Program, see generally Registration & Attestation, supra note 165.

182. Section 4 of FERA is entitled "Clarifications to the False Claims Act to Reflect the Original Intent of the Law." In an effort to bring clarity to the law in the face of case law that had raised questions as to the Act's scope, these FERA provisions enacted several changes that expanded FCA liability by relaxing the Act's presentment requirement, broadening the range of property covered by the Act, and removing the element of intent formerly required for a finding of liability under the Act. See Fraud Enforcement and Recovery Act Increases the Scope of False Claims Act Liability, Arnold & Porter LLP (June 2011), available at http://www.arnoldporter.com/resources/documents/Advisory_FraudEnforcement&Recovery

FCA provisions that directly impact VBP programs. These amendments — dealing with defendant "intent" and the circumstances governing "overpayments" —set up fraud landmines for VBP participants. In short, defendants can now be held liable for submitting false claims, even in the absence of fraudulent intent, as long as the defendant's false statement is material to the false claim. Moreover, FERA raised the stakes for providers retaining improperly obtained federal healthcare program reimbursements under new standards governing "reverse false claims." This section examines how these FERA-based FCA amendments impact providers submitting quality data for incentive or penalty-driven reimbursements.

1. Elimination of "Intent" Language Broadens FCA Reach

The FCA's civil liability provisions seek to hold accountable those providers who submit a false claim and/or make a false statement in connection with a claim for reimbursement.[183] In the VBP context, a violation could arise where a provider submits false or inaccurate electronic quality data and/or supporting documentation in order to obtain an incentive payment or avoid a penalty under a P4P program. FERA amendments have greatly simplified the government's enforcement responsibilities to ensure VBP program integrity by making the actor's state of mind essentially irrelevant to false claim liability; rather, now the government only needs to establish that the false information provided was material to the claim submitted in anticipation of government reimbursement.

Of tremendous significance to the healthcare community, the FERA amendments delete FCA language requiring intent to defraud the government as demonstrated by the use of a false record or statement to get a false claim paid.[184] To that end, FERA effectively reversed the unanimous decision of the Supreme Court in the Allison Engine case, which required the government to prove that a defendant, when using a false record or statement "to get" a false claim paid or approved "by the government," intended for the government to pay that claim in order to establish liability under (former) Section 3729(a) (2) of the FCA.[185] In essence, Allison Engine stood for the proposition that, in order to establish liability under the FCA, there must be a clear link between a false claim and payment or approval by the government.[186] FERA eliminated this intent

ActIncreasesTheScope_060509.pdf. See also Nadler, supra note 91 and Rhoad, supra note 91.

183. See 31 U.S.C. §§3729-33 (2006).

184. 31 U.S.C. § 3729(a)(2) (2006) (current version at § 3729(a)(1)(B) (2009)). See generally Rhoad, supra note 91, (discussing further the statutory amendment of the FCA).

185. Allison Engine Co. v. United States ex rel. Sanders, 553 U.S. 662, 663 (2008).

186. Rhoad, supra note 91; see also False Claims Act Expansion to Affect Health Care

requirement by removing both the "to get" and "by the government" language from Section 3729(a)(2) (now § 3720(a)(1)(B), as amended).[187]

Consequently, FERA replaced the intent requirement with a lesser "materiality" requirement. Now, all that is required to fall within the bounds of the FCA's reach is for one to "knowingly make[], use[], or cause[] to be made or used a false record or statement material to a false or fraudulent claim."[188] "Material" is now statutorily defined as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."[189] So, as applied to a provider submitting false quality data to satisfy VBP requirements, the FCA would introduce liability risks if the claim-related information provided to CMS was material to claim reimbursement to earn an incentive payment (or to avoid negative reimbursement adjustment).

The materiality provision's reach is all-encompassing: quality data submitted to CMS to satisfy the requirements of the government's VBP programs would always be "material" to the reimbursement since the quality data's purpose is to determine the provider's reimbursement. Moreover, the data submitted would routinely meet the materiality standard pursuant to the statute as such information would always "tend to influence" and would otherwise always be "capable of influencing" the government's decision to reimburse the provider.

2. FERA Expands Provider Overpayment Obligations for FCA "Reverse False Claims"

As noted, CMS has announced that audits of provider records will be conducted to ensure that payments were legitimately earned.[190] In fact, in its 2012 Work Plan, the OIG set forth a new auditing agenda that includes a focus on overpayments of Medicare inpatient and outpatient reimbursements to acute care hospitals. The Work Plan states that the

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Providers, Pepper Hamilton LLP (June 30, 2009), available at http://www.pepperlaw.com/publications_update.aspx?ArticleKey=1535.

187. Rhoad, supra note 91, at 6; Nadler, supra note 91, at 30. This left what the Allison Engine Court cautioned is tantamount to an "almost boundless . . . all-purpose antifraud statute." 533 U.S. at 669, 672.

188. § 3729(a)(1)(G) (emphasis added).

189. § 3729(b)(4); see also New False Claims Act Amendments Strengthen Significant Impact Health Care Entities and Their "Obligations" Regarding Overpayments, CROWELL MORING LLP (May 28, 2009), available at http://www.crowell.com/NewsEvents/AlertsNewsletters/all/New-False-Claims-Act-Amendments-Significantly-Impact (explaining "[a]lthough 'materiality' has long been considered an implied requirement to establish FCA liability by most courts, this statutory change now inserts the requirement into the black letter law itself.").

190. See supra footnotes 88-90 and accompanying text.

agency will "review Medicare payments to hospitals to determine compliance with selected billing requirements."[191] Further, the OIG "will use the results of these reviews to recommend recovery of overpayments."[192] The Work Plan describes an auditing method based on computer matching and data mining techniques to select hospitals that may be at risk for overpayments.[193] The government is prioritizing the identification and pursuit of improperly retained payments for Medicare services. Presumably, the $850 million in reimbursements CMS has set aside for FY 2013 for hospitals satisfying performance criteria of VBP programs comprise a significant component of CMS hospital payments targeted for audits under the Work Plan agenda. [194]

The FCA is the legislative vehicle authorizing the government's recoupment of improperly retained payments from the Medicare program. The Act sets forth that an "obligation" to pay includes "an established duty, whether or not fixed, arising . . . from the retention of any overpayment."[195] Under FERA's amendment, mere retention of an overpayment where an obligation to repay existed in no uncertain terms amounts to a violation of an "established duty" and consequently gives rise to potential liability under the FCA.[196] Moreover, under the 2009 FERA amendments, there is no longer a need for a person to have taken an affirmative act – submission of a false statement or record – in order to have concealed, avoided, or decreased an obligation to the government under the statute.[197] Congress clarified the obligation to refund government monies with FERA in 2009 and then again with PPACA in 2010. These two statutes amended the civil False Claims Act by expanding the scope of the obligation to refund an overpayment and rendering retention of funds less defensible.[198] The FCA provisions governing providers' obligations to return government funds carry significant and unique implications for VBP program participants.[199]

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191. See 2012 WORK PLAN, supra note 86 at I-5.

192. Id.

193. Id.

194. Administration Implements New Health Reform Provision, supra note 17.

195. 31 U.S.C. § 3792(b)(3).

196. See id.; see also Rhoad, supra note 91, at 18.

197. 31 U.S.C. § 3729(a)(1)(G) is the authority for the "reverse false claim" provision. For a discussion, see generally Nadler, supra note 91; Rhoad, supra note 91.

198. 31 U.S.C. § 3729(a)(1)(G), amended by FERA. PPACA's provision impacting overpayment obligations can be found at 42 U.S.C. § 1320a-7k(d). For a discussion, see generally Hilgers & Welch, supra note 77; Stephen J. Chananie et al., Disclosing and Refunding Overpayments in Healthcare Cases, 24 THE HEALTH LAWYER 16, 16 (Feb. 2012), available at http://www.americanbar.org/content/dam/aba/publishing/health_lawyer/health_mo_premium_hl_healthlawyer_v24_2403.

199. For a thorough discussion of overpayment issues, see generally Chananie et al., supra note 198.

The DOJ has historically taken the position that the "reverse false claim" or "overpayments" provision applies to the knowing retention of payments from federal programs when the recipient had not rightfully earned them.[200] With the passage of FERA, Congress endorsed the DOJ's purported application of the FCA and validated a "reverse" false claims theory[201] by introducing new statutory language governing the provider's "obligation," or legal responsibilities with respect to overpayments.[202] FCA liability arises when a person "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government."[203] The pre-FERA FCA statute already established that "knowledge" includes not only actual knowledge, but also acting in "deliberate ignorance" or in "reckless disregard of the truth or falsity" of information in a claim or record.[204] Rather, regardless of whether overpayments were retained conscientiously, they are nonetheless illegally retained and the recipient of the funds is within the FCA's reach.

Moreover, PPACA further expanded the scope of the obligation to return an overpayment by introducing an aggressive time limit in which providers must disclose and return funds. Specifically, under PPACA, any Medicare funds received or retained to which a healthcare provider is not entitled must be reported and refunded within sixty days from the date the overpayment is "identified,"[205] or the provider risks liability under the FCA.[206] In the context of VBP programs, if a hospital receives an incentive payment, and subsequently realizes that the data upon which the incentive payment was based was false or otherwise did not accurately represent the provider's performance scores, the incentive payment would amount to an overpayment and the sixty-day clock for disclosure and return would begin

200. See id.

201. See id. The Senate Report accompanying FERA specifies that it was a DOJ recommendation that Congress make it a violation of the FCA "once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment." Accordingly, as the Senate Report stresses, "any knowing and improper retention" of an overpayment would be actionable, if the overpayment is retained "beyond the final submission of payment as required by statute or regulation." Id.

202. See 31 U.S.C. § 3729(a)(1)(G). For a discussion, see generally Hilgers & Welch, supra note 77; ALSTON & BIRD LLP, OVERPAYMENT LIABILITY UNDER THE "REVERSE FALSE CLAIMS" ACT (2010), available at http://www.alston.com/files/Publication/e2478934-2075-4e64-a0c8-4e2aca4c2ccf/Presentation/PublicationAttachment/1e0274e4-65a0-4355-94c2-4f9e520ca90d/FCA%20Overpayment.pdf.

203. See 31 U.S.C. § 3729(a)(1)(G).

204. 31 U.S.C. § 3729(b)(1)(A) as amended by FERA.

205. 42 U.S.C. § 1320a-7k(d)(2) (providing that disclosure and refunding is due by the date any corresponding cost report is due (if applicable)). The report must include a written explanation of the reason why the overpayment occurred. Id. This provision went into effect immediately upon enactment on March 23, 2010. 42 U.S.C. § 1320a-7k(d).

206. 42 U.S.C. § 1320a-7k(d)(3).

to run.[207] Such an overpayment would potentially amount to a (reverse) false claim and subject the provider to FCA penalties.[208]

In February 2012, CMS addressed several unanswered questions concerning overpayment obligations (and in particular, the new sixty-day rule) by proposing the rule implementing Section 6402 of PPACA[209] (the "Proposed Rule") governing overpayment obligations.[210] The Proposed Rule offered much needed clarification and also granted some concessions to providers; however, the fraud risks posed by the Proposed Rule remain severe and CMS clearly seeks to incentivize diligence through these proposals.[211]

Although the requirement to refund an overpayment already exists in federal law, the Proposed Rule clarifies what constitutes "identification" of an overpayment, as well as the details regarding when and how an overpayment must be returned. The Proposed Rule does signify CMS' acknowledgement that overpayments can be difficult to assess and, even with diligent compliance oversight to identify improperly retained funds, the internal investigation process (and particularly confirming and

207. Similarly, if, rather than earning an incentive payment, a provider met program criteria requiring enumerated benchmark or performance scores in order to avoid a reimbursement penalty, and the provider later discovered that the data upon which reimbursements were based was inaccurate (and benchmarks were in fact not met), this too would constitute a scenario giving rise to a reverse false claim if the sixty-day limit was not satisfied. See Chananie, supra note 198, at 16-17.

208. In addition to linking potential penalties under the FCA to the retention of overpayments, PPACA also amended the Civil Monetary Penalties Law to allow treble damages and additional administrative fines to be imposed on persons who have knowledge about an overpayment and fail to make a timely report and refund. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402 (2010) (adding new subsection a(10) to 42 U.S.C. § 1320a-7k).

209. § 1128J(d).

210. Medicare Program: Reporting and Returning of Overpayments, 77 Fed. Reg. 9179 (proposed Feb. 16, 2012) [hereinafter OVERPAYMENT RULE] available at http://www.gpo.gov/fdsys/pkg/FR-2012-02-16/pdf/2012-3642.pdf. The Proposed Rule only applies to Medicare Part A and Part B providers and suppliers. However, the preamble emphasizes that the other stakeholders identified in Section 6402 of PPACA may nonetheless be subject to civil penalties and exclusion for violation of the statute. The sixty-day comment period ended April 16, 2012 and the Final Rule is pending as of the date of this article. See id.

211. For a discussion of the Proposed Rule, see e.g., Paul W. Pitts & Debra A. McCurdy, CMS Proposed Rule on Reporting and Returning of Medicare Overpayments Under the ACA, HEALTH INDUSTRY WASHINGTON WATCH (Feb. 28, 2012), available at http://www.healthindustrywashingtonwatch.com/2012/02/articles/regulatory-developments/hhs-developments/cms-proposed-rule-on-reporting-and-returning-of-medicare-overpayments-under-the-aca/#more; Marcus C. Hewitt, CMS Issues Proposed Rule on 60-Day Reporting/Repayment Obligation for Overpayments to Medicare Providers, WILLIAMS MULLEN (Feb. 24, 2012), available at http://www.martindale.com/health-care-law/article_Williams-Mullen_1454642.htm.

quantifying the overpayment) might reasonably take longer than sixty days.[212] As such, the Proposed Rule extends some relief to providers from an expectation that they complete the investigation, identify relevant claims, and process a refund all within sixty days.

Rather, CMS proposes to stay the sixty-day clock (meaning, the point at which the overpayment is "identified" per the statute) until the provider or supplier has had a reasonable opportunity to investigate potential overpayments.[213] The Proposed Rule anticipates circumstances in which a provider will receive information that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If that inquiry uncovers an overpayment, the sixty-day "clock" begins to run such that the provider then has sixty days to report and return the overpayment.

CMS is serious about providers carrying out their "reasonable inquiry" obligation in earnest. Specifically, providers are expected to conduct their inquiry "with all deliberate speed after obtaining the information."[214] Recalling the FCA's definition of "knowledge" of an overpayment to include acting in reckless disregard or deliberate ignorance of receipt of an overpayment reinforces the "all deliberate speed" language holding providers to a high standard of investigative diligence. As such, the Proposed Rule establishes that providers act at their own peril if they do not have adequate systems in place, such as internal audit programs, to timely identify potential overpayments.[215] These obligations would seem to necessitate heightened levels of due diligence as a part of a rigorous compliance program.

The proposed "self-reported overpayment refund process"[216] introduces a

212. See generally OVERPAYMENT RULE, supra note 210.

213. Hewitt, supra note 211; see also Pitts & McCurdy, supra note 211.

214. See generally OVERPAYMENT RULE supra note 210.

215. See e.g. Thomas Hess & Tyler Williams, DINSMORE & SHOHL LLP, CMS Proposes 60 Day Repayment and Overpayment Regulations, DINSMORE & SHOHL LLP (Mar. 7, 2012), available at http://www.jdsupra.com/post/documentViewer.aspx?fid=a563663d-ef12-4600-b4db-d5c2ce907a0d; Thomas Beimers, CMS Releases Proposed Rule on PPACA's 60 Day Report and Repay Requirement, BEYOND HEALTH REFORM (Feb. 15, 2012), available at http://beyondhealthcarereform.com/2012/02/cms-releases-proposed-rule-on-ppaca%E2%80%99s-60-day-report-and-repay-requirement/. See infra Section VI.

216. See Hewitt, supra note 211; see Pitts & McCurdy, supra note 211. Under the Proposed Rule, the existing voluntary refund process in Chapter 4 of the Medicare Financial Management Manual will be renamed the "self-reported overpayment refund process." This is the process providers will use to effectuate refunds. CMS contemplates a standardized form to be used for repayments, but does not have one yet. See Hess & Williams, supra note 215; see also Pitts & McCurdy, supra note 211. PPACA Section 6402 requires providers who receive a Medicare or Medicaid overpayment to report and return the overpayment to the program within 60 days of identifying the overpayment, or, for entities required to submit cost reports, by the later due date of the applicable corresponding cost report. See generally Beimers, supra note 215.

significant regulatory burden and bears similarities to the existing OIG and CMS self-disclosure protocols for anti-kickback and Stark law violations.[217] CMS also further defined the temporal scope of a provider's investigative responsibilities with a proposed ten year look back period. That is, overpayments must be reported and returned if a person identifies it within ten years of the date it was received.[218] With these provisions, the government makes clear its expectations that providers implement adequate policies and procedures to monitor payments received from federal healthcare programs and identify any overpayments in order to avoid liability risks.

V. HOSPITAL/ PHYSICIAN ALIGNMENT CRITICAL TO VBP, BUT LEGALLY CHALLENGING TO ACHIEVE

As discussed at length herein, Value Based Purchasing is indeed poised to transform the nation's healthcare reimbursement model. This paper has discussed each aspect of the VBP template set forth by CMS in its Roadmap to Implementing VBP,[219] examining the progression of VBP from "pay for reporting" stages to now robust "pay for performance" programs that extend opportunities to hospitals in 2013 to earn incentive payments for performance achievements. Moreover, HHS' commitment to transparency and the agency's steady movement along the VBP continuum toward "efficient resource use" and, ultimately, "paying for value," has been recognized herein.[220] Yet, CMS' VBP template includes one additional element not yet discussed, but which is undoubtedly critical to the transformative potential of VBP. In short, hospital-based care is not likely to reach its peak quality improvement potential if the hospital's organizational interests are not well aligned with the interests of the physicians who deliver the care within its walls. This section examines the

217. A disclosure through the CMS Self-Referral Disclosure Protocol (SRDP) tolls the 60-day deadline for returning overpayments related to physician self-referrals. The preamble to the Proposed Rule clarifies that a SRDP submission only tolls the 60-day deadline for repayment and does not toll the 60-day deadline for reporting the overpayment through the self-reported overpayment refund process. Unlike an SRDP submission, a submission through the OIG Self-Disclosure Protocol would suspend the repayment obligation and the reporting obligation. See Beimers, supra note 215.

218. See generally Pitts & McCurdy, supra note 211; Beimers, supra note 215. The ten-year look-back matches the outer limit of the statute of limitations for the False Claims Act. CMS also proposes to amend the reopening rules to be consistent with the ten-year look-back for the 60-Day Rule. Under the Proposed Rule, reporting and repayment would be required for all overpayments identified within ten years of receipt. This is a significant increase in potential exposure and recordkeeping obligations. In accordance with this timeframe, CMS is also proposing to extend its reopening period to ten years.

219. See CMS ROADMAP, supra note 1; see also supra Section I.

220. See supra Section I.

critical role of hospital/physician alignment in the success of VBP programs, as well as the legal obstacles to introducing shared financial rewards in pursuit of improved care.

CMS has recognized that significant operational and legal obstacles run counter to hospital/physician alignment, which will consequently require a collaborative effort across industry stakeholders to harmonize misaligned interests.[221] Regarding the roles and expectations of hospitals and physicians in working toward alignment, CMS has stated that "[p]hysicians and providers would need to reorganize themselves in order to achieve the best clinical and financial outcomes."[222] As discussed herein, this may require new compensation models and/or the introduction of shared savings programs. CMS acknowledges that in order to support new payment models like VBP, modifications to the physician self-referral rules may be necessary to permit hospitals to reward physicians for improving quality and efficiency in their local health care delivery settings.[223]

CMS recognizes that VBP is characterized by the absence of financial incentives that directly benefit physicians so as to motivate physician performance toward care improvement. Indeed, CMS anticipates that rewarding hospitals with incentive payments based primarily on the performance of those hospitals' professionals will not sufficiently motivate the physicians to improve the quality of care they deliver if they have no financial stake in changing their own behavior.[224] Generally, under the traditional FFS model, doctors use their discretion to order the care they deem necessary, but then face no discernible financial consequences for the cost of that care.[225] As such, physician payment does not tend to support or encourage the new emphasis on value.[226] With the transition from FFS to

221. See CMS ROADMAP, supra note 1, at 1. CMS proposes to work in partnership with physicians, providers, beneficiaries, Congress and other stakeholders to create a healthcare financing system that promotes joint clinical and financial accountability. The agency will "need to restructure the payment systems in order to provide incentives for physicians and providers to work together to develop new ways to deliver high quality, efficient care."

222. See id.

223. See id.

224. See Youngstrom, supra note 93.

225. See Anderson & Wilson, supra note 45, at 30. FFS encourages overuse of services and without regard to either the impact of service delivery on patient outcomes or quality of care processes. See also ALICE G. GOSFIELD, BOLSTERING CHANGE: PHYSICIAN COMPENSATION FOR QUALITY AND VALUE (Alice G. Gosfield, Ed., Thomson Reuters forthcoming 2012) [hereinafter BOLSTERING CHANGE]. Moreover, where FFS rewards overuse, capitation is an historic model that rewards underuse. If either of these was capable of producing high quality care, P4P programs would not be necessary. See also Alice G. Gosfield, Compensation for Quality: The Next Inevitable Step, GROUP PRACTICE J. 11, 11 (May 2008) available at http://www.gosfield.com/PDF/Gosfield_May_2008_GPJ%5B1%5D.pdf.

226. See Anderson & Wilson, supra note 45, at 30.

VBP, this reality is not significantly altered for physicians; under hospital VBP, physicians are not directly impacted by financial penalties (negative reimbursement adjustments) levied against the care institutions where they practice.[227]

Misaligned hospital/physician interests threaten to limit performance achievements under the VBP program. In particular, typical hospital/physician relations[228] do not encourage optimal levels of care coordination.[229] The quality and efficiency of care is often compromised when splintered across multiple provider locations and certainly it is more difficult to improve performance scores.[230] Moreover, in a fragmented care setting, both provider and physicians have limited tools to positively influence one another's practice patterns to achieve superior patient outcomes.[231] For Hospital VBP especially, hospitals will need to enlist physician support to meet quality targets and earn the VBP incentive payments.[232]

Hospital administrations' success in influencing physician behavior can largely depend on the physician compensation models in place.[233] Motivating physicians to improve care delivery is most difficult when the physicians are members of an independent medical staff and otherwise not

227. See id. It is noted that for physicians participating in physician P4R or P4P they are incentivized to improve their own record of care delivery. See supra note Section I. Consequently, physicians should become increasingly interested in improving quality outcomes as the physician VBP program is implemented in 2015. Moreover, some of the quality measures in the physician and hospital program overlap or align such that improved physician quality of care would positively impact both the physician and the hospital. However, there remain gaps as between and among the physician and hospital quality measures, as well as a temporal gap between implementation of their respective VBP programs. See id.

228. See AM. HOSP. ASSOC., TRENDWATCH: CLINICAL INTEGRATION- THE KEY TO REAL REFORM 1 (Feb. 2010), available at http://www.aha.org/research/reports/tw/10feb-clinicinteg.pdf (explaining that in the common model physicians use hospital facilities and rely on hospital staff to provide their services but the medical staff is not employed by the hospital).

229. See Anderson & Wilson, supra note 45, at 30.

230. See AHA, supra note 228, at 1-2. Multiple studies show the fragmentation of care problem .A New England Journal of Medicine study concludes that the typical patient with multiple chronic conditions sees as many as three primary care physicians and eight specialists in seven care settings. A Robert Wood Johnson Foundation study reportedly found that for every 100 Medicare patients treated, each primary care physician would typically have to communicate with ninety-nine physicians in fifty-three practices in order to coordinate that patient's care. See id. at 1-2.

231. See id. at 2.

232. See Anderson & Nedza, supra note 8, at 60.

233. See generally BOLSTERING CHANGE, supra note 225 (discussing generally how compensation models respond to various payment systems).

employed by the hospital.[234] However, even with an employment arrangement, frustrations to alignment may persist as contracts may still incentivize quantity to the detriment of quality care or patient satisfaction goals.[235] Thus, as new payment reforms like VBP orient hospitals and health systems toward coordinated and integrated care, most of these providers will need to alter relationships with physicians.[236] In order to most strategically position itself for a shared savings program, a hospital should successfully engage a physician group, regardless of employment status, who will commit to providing a new model of evidence-based, high quality, efficient care.[237]

Even where hospital administration and physicians alike agree that alignment is desirable, they face significant legal obstacles in undertaking shared savings arrangements. The rising popularity and health industry interest in the Accountable Care Organization (ACO)[238] model offers a compelling illustration as to why shared savings is both critical to VBP success, yet difficult to legally structure. That is, the potential of an ACO to demonstrate improved care through shared savings is dependent on the ACO's "built-in" waivers of fraud violations (participants are legally excused from what would amount to illegal kickbacks and remuneration

234. See Anderson & Nedza, supra note 8, at 60 (suggesting that without an employment arrangement, it is difficult in practice for hospitals to influence physicians by "simply coaxing, cajoling, scolding"). For additional discussions regarding hospital/physician alignment challenges as they relate to compensation models, see Anderson & Wilson, supra note 45 (recommending how to structure compensation to maximize quality performance under new payment models); Youngstrom, supra note 93 (hospitals that employ physicians are better situated to encourage and motivate performance but even the employment model may not provide enough incentive to meet new reimbursement benchmarks).

235. See Lindsay Dunn, Bridging the Gap Between Fee-for-Service and Value-Based Care Starts with Physician Feedback, BECKERS' HOSPITAL REVIEW (Feb. 15, 2012), available at http://www.beckershospitalreview.com/hospital-management-administration/bridging-the-gap-between-fee-for-service-and-value-based-care-starts-with-physician-feedback.html; see also Anderson & Nedza, supra note 8, at 36; Anderson & Wilson, supra note 45, at 38 (stating that under the new models of care, employment by itself will not result in the health care delivery changes that are required to perform well under VBP).

236. See Dunn, supra note 235 (noting increasing physician concern regarding reimbursement changes has caused physicians to "run for the shade" and seek hospital employment where they are typically welcomed as part of hospital integration strategy).

237. See Anderson & Wilson, supra note 45, at 38.

238. For an overview of ACOs, see Accountable Care Organizations, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/ACO/; for an informative discussion regarding ACOs, see Jenny Gold, Accountable Care Organizations, Explained, NAT'L PUB. RADIO (Jan. 2012), available at http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained.

under Anti-kickback and Stark laws, respectively).[239] This begs the question as to how hospitals seeking to extend financial rewards to physicians in pursuit of VBP incentive payments can do so without running afoul of the Stark law and other fraud landmines in the absence of such waivers.[240]

There are options for providers who are not part of an ACO but who wish to arrange for shared savings for quality improvements. The OIG has endorsed a Pay for Quality model that recognizes narrow circumstances under which shared savings in a VBP program is permissible. Advisory Opinion 8-16 (AO 8-16) permits the creation of a new legal entity, in which all physicians who have been on a hospital's active medical staff for at least a year may join, and may legally contract with a hospital to provide designated services that will purportedly improve quality and promote efficiency of care.[241] In turn, the Pay for Quality model permits payments to the entity on a per capita basis as a percentage of P4P or VBP dollars earned by the hospital.[242] The Pay for Quality structure would appropriately and effectively incentivize multiple physician specialties regardless of physician employment status to improve performance outcomes pursuant to VBP.[243] The OIG has approved multiple shared savings scenarios to reduce the legal risks associated with shared savings programs.[244] However, these solutions are not without risk; legal experts still warn that other fraud and abuse laws must be carefully navigated in shared savings pursuits.[245]

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239. Julie E. Kass & John S. Lineham, Fostering Healthcare Reform Through a Bifurcated Model of Fraud & Abuse Regulation, 5 J. HEALTH & LIFE SCI. LAW, 108-16 (Feb. 2012), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM12/papers/X_kass_jhl_article.pdf.

240. See e.g. Anderson, supra note 69 (discussing how CMS and OIG recognize the importance of gain-sharing as a component of VBP); AHA Trendwatch, supra note 225 (discussing legal barriers to savings including antitrust laws, Stark laws, Civil Monetary Penalty laws and Anti-kickback laws); See Douglas Hastings, et al., Waivers Under the Medicare Shared Savings Program: An Outline of the Options, AM. HEALTH LAWYERS ASS'N, available at http://www.healthlawyers.org/About/Leadership/BoardCommittees/Documents/ACO_ACOWaiver Options_Final.pdf (discussing in-depth examination of how to structure legal arrangements under ACOs).

241. DEP'T OF HEALTH AND HUMAN SERVS., OIG ADVISORY OPINION NO. 08-16 9 (2008) [hereinafter OIG ADVISORY OPINION].

242. See id. at 4; see also Anderson & Van Leer, supra note 15.

243. OIG ADVISORY OPINION, supra note 241 at 5; see Anderson & Wilson, supra note 45.

244. See Anderson & Van Leer, supra note 15; Anderson, supra note 69.

245. For a brief overview of other fraud and abuse laws that pose risks arising out of shared savings plans, see Jennifer W. Payton & Lawrence W. Vernaglia, Managing the Legal Risks Associated with Collaborating on Quality: How Can We Do the Right Thing and Remain Compliant? HCCA QUALITY OF CARE COMPLIANCE CONFERENCE (Oct. 13, 2009), available at http://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Quality_of_Care_Compliance_Conference/701_Vernaglia_Payton.pdf.

After AO 8-16 was published, CMS proposed an exception to the Stark law that would build upon the Opinion's momentum toward legalizing opportunities for savings arrangements.[246] While the fate of the Stark exception remains uncertain, CMS is managing several demonstrations and initiatives seeking to further the goals of healthcare reform and explore new ways to encourage sharing of financial rewards for improved performance.[247] Through increased alignment, CMS ultimately aims to "break down" the "artificial silos of care and payment based on the structure of the Medicare Part A and B Trust Funds."[248] CMS explains that provider-based quality incentive and shared savings plans can potentially increase provider communities' understanding and appreciation of the need to have joint accountability in their clinical and financial outcomes, which are foundational tenants of VBP.[249]

VI. VALUE-DRIVEN REIMBURSEMENT CALLS FOR COMPLIANCE OVERHAUL

As discussed, the new quality-based reimbursement model introduces a number of novel fraud risks that must be carefully monitored and managed to avoid financial loss and liability exposure under the FCA. Compliance professionals' leadership will be critical in facilitating hospitals' transitions from the longstanding FFS, quantity of care-based focus to a VBP system with a focus on value. In fact, Daniel R. Levinson, head of the OIG, has called upon hospitals to place quality issues at the forefront of their compliance operations. At the 2010 Health Care Compliance Association's

246. See Health Care Alert: Proposed 2009 Physician Fee Schedule Would adopt Gainsharing Stark Exception, ROPES & GRAY (July 7, 2008), available at http://www.ropesgray.com/files/Publication/5463b9cb-994d-4c8d-9c40-00c16b1688b2/Presentation/PublicationAttachment/1f108e99-a299-4044-a099-0a739527de47/070708_HC_Proposed2009PhysicianFeeSchedule.pdf (explaining that in 2009, the Stark Exception for Incentive Payment and Shared Savings Plans was proposed). This proposal set forth a specific exception to the physician self-referral rules in the CY 2009 physician fee schedule proposed rule. See CMS ROADMAP, supra note 1. For a thorough examination of the proposed exception, see also Payton & Vernaglia, supra note 245. The proposed exception is aimed at permitting appropriate quality improvement and cost savings programs to the extent they guard against a host of fraud vulnerabilities. The proposed exception lists stinting; steering; cherry-picking; gaming; paying for referrals/volume increases; and quicker sicker issues as potential fraud threats that the Exception should theoretically protect against. Critics suggest that while it is a positive development, its restrictive terms may ultimately limit its utility and providers may be ultimately reliant on Stark law statutory exceptions. Payton & Vernaglia, supra note 245.

247. These include, for example, the Post Acute Care Reform Demonstration; Medicare Hospital Gain-sharing Demonstration; the Physician Hospital Collaboration Demonstration; Acute Care Episode Demonstration. See generally CMS ROADMAP, supra note 1, at 16-18.

248. See id. at 16.

249. See id.

(HCCA) annual event, he implored compliance professionals to focus on transparency, quality and accountability as they prepare for and carry out reform initiatives.[250] Levinson suggested that the government's new payment and delivery models—with specific reference to VBP—require a fresh examination of fraud and abuse risk from the compliance officer's perspective.[251]

A. Compliance Leadership Opportunities in the Quality Agenda

In his address to the HCCA, Levinson set forth a number of indicators to determine if compliance professionals are on the right track in their compliance efforts to prepare for payment reforms.[252] These included, among others: the extent to which the compliance department understands that quality of care is increasingly integral to payment; whether compliance professionals are present during conversations and involved in decisions about reimbursement arrangements in the organization; whether the compliance department has the expertise to address quality-related compliance issues; and whether the compliance department is focused on identifying and addressing new fraud and abuse risk areas that may arise as new payment systems unfold.[253] In order to respond to new risks accordingly, hospital compliance departments must restructure their programs where necessary to reflect quality's role as the driving force in the organization's compliance-related matters.[254]

One of the greatest obstacles compliance departments face in their efforts to integrate quality into their operations concerns the traditionally fragmented organizational structure of healthcare institutions.[255] Typically, hospitals have maintained separate departments for quality improvement, corporate compliance, and risk management.[256] Each of these is concerned

250. DANIEL R. LEVINSON, HIGHLIGHTS OF KEYNOTE ADDRESS DELIVERED BY DANIEL R. LEVINSON, INSPECTOR GENERAL OF DHHS, HEALTH CARE COMPLIANCE ASS'N ANNUAL COMPLIANCE INST. (Apr. 19, 2010) [hereinafter COMPLIANCE REPORT], available at http://oig.hhs.gov/testimony/docs/2010/HCCAIGKeynoteSummary.pdf. Levinson asked compliance professionals to consider fraud and abuse risks that arise out of the implementation of new payment systems with specific reference to value-based purchasing as one such new system requiring diligent fraud risk management. Id.

251. Id.

252. Id.

253. Id.

254. See generally Anderson & Nedza, supra note 8.

255. See D. Scott Jones, Combining Disciplines: Quality Improvement, Risk Management and Corporate Compliance, J. HEALTH CARE COMPLIANCE (2007), available at https://csuglobal.blackboard.com/bbcswebdav/library/Article%20Reserve/HCM370/Combining%20disciplines%20-%20Making%20the%20connection%20between%20compliance%20risk%20and%20quality%20management.pdf.

256. See id.

to varying extents and from different perspectives with the quality mission.[257] The health care reform agenda involves efforts to transition our fragmented care delivery system to an efficient, well-integrated delivery model.[258] Operating in "silos" threatens to prevent hospitals from delivering coordinated care that is necessary to meet quality and cost demands of reform.[259] The OIG Chief Counsel Lewis Morris has eschewed the "siloing of responsibility" and underscored the importance of "the different components of a health care organization need[ing] to communicate and exchange information with each other."[260] If it is not feasible to combine these departments, compliance professionals should consider seizing upon the opportunity to facilitate greater collaboration to accomplish objectives related to quality improvement.[261] VBP reforms could greatly benefit from departmental collaboration, under the leadership of compliance professionals, as the new payment model undoubtedly depends on coordinated care to reach its quality improvement potential.

B. Compliance Role in Quality Data Management

Several of Levinson's directives urge compliance professionals to be involved in the data management aspects of their VBP program. For example, he suggested that compliance departments ensure that the organization's system for charting, collecting and reporting quality data and clinical documentation is accurate, complete and justifies payment.[262] Moreover, he asked if hospitals are using data mining and other techniques to detect improper claims.[263] The message is clear that the marriage of payment and quality under VBP now requires that compliance monitoring reach into the unchartered compliance territories of patient outcomes and data integrity.[264]

Data integrity issues arising out of quality reporting present some nontraditional challenges for a hospital compliance department. Compliance departments need to appreciate the billing dynamics of quality reporting compared to traditional claims-based billing. Whereas general

257. See id.

258. Sabrina Rodak, Breaking Down Silos to Improve Patient Flow, Hospital Efficiency, BECKER'S HOSPITAL REVIEW (Mar. 12, 2012), available at http://www.beckershospitalreview.com/capacity-management/breaking-down-silos-to-improve-patient-flow-hospital-efficiency.html.

259. Id.

260. Anderson & Nedza, supra note 8, (quoting Lewis Morris, Chief Counsel to the OIG).

261. See Jones, supra note 255.

262. See COMPLIANCE REPORT, supra note 250.

263. See id.

264. See Anderson, supra note 38.

billing errors are discrete, quality reporting errors can create systemic problems and corrupt cumulative quality performance scores.[265] Reimbursement for reporting programs including VBP occurs at the end of a reporting year based on an entire set of reported codes as opposed to payment on an ongoing basis for individual claims.[266] Any fraud issues pertaining to the data upon which payments were based jeopardizes the entire payment; as such, incorrect data could compromise the integrity of the scores for individual quality measures, multiple quality measures and/or the Total Performance Score[267] upon which reimbursements are based.[268]

As noted previously in the discussion regarding risk of fraud arising out of VBP programs,[269] maintaining and ensuring the integrity of quality data generated and submitted to CMS is critical to avoiding liability under the FCA. Compliance departments are instrumental in monitoring data quality and validity.[270] Compliance professionals should maintain a role in reviewing patient population data for the designated VBP performance periods to make sure all patients that fall within the various quality measure criteria are in fact included. Corporate compliance should maintain robust processes to identify gaps or inaccuracies in quality data and analyze the issues with clinical quality and staff.[271] These oversight mechanisms might be best accomplished through structured validation reviews. The primary purpose of validation reviews is to ensure that the quality data could be recreated under auditing circumstances.[272] Ensuring the integrity of quality data before submitting it to CMS is consistent with the OIG's emphasis on employing internal procedures that screen for improper claims prior to filing, and may protect against FCA liability.[273]

Moreover, in light of the evolving landscape for quality measurement and reporting, it is important that providers develop an infrastructure to track and manage the proliferation of quality measures. Compliance professionals should evaluate and prioritize the clinical quality measures in the context of an overall quality strategy.[274] In particular, such a strategy

265. See Daniel F. Shay, Physician and Hospital Quality Reporting Fraud: Risk and Compliance Methods, HEALTH LAW HANDBOOK section 3.4 (Alice G. Gosfield, ed., 2010), available at http://www.gosfield.com/PDF/Shay.QualityReportingFraud.pdf.pdf.

266. See id.

267. See Section IB, supra footnotes 55-59 and accompanying text.

268. See Shay, supra note 265, at 10-11.

269. See supra Section II.

270. See Thorpe, supra note 164, at 33.

271. See Shay, supra note 265, at 10; see also Watt & Chase, supra note 95, at 18 (recommending auditing and monitoring of quality measures).

272. See Watt & Chase, supra note 95.

273. See COMPLIANCE REPORT, supra note 250.

274. Deloitte, Organizing to Drive Quality Improvement through Measurement (Oct.

would involve a procedure to accommodate newly announced quality measures, which CMS has cautioned could be issued in as few as sixty days prior to the commencement of the applicable performance period under the VBP program.[275]

C. Compliance Role in Tracking Overpayments and Preparing for Quality Data Audits

As previously discussed, CMS is expected to audit hospital data arising out of VBP claim submissions. Providers that choose to report quality data through the attestation tool[276] are advised to retain medical records and all supporting documentation for at least six years following attestation.[277] Moreover, any assumptions made by clinical or administrative staff when evaluating and entering quality data into their EHR or attestation tool, should be well documented since the descriptive language for some quality measures leaves room for varying interpretations.[278] Compliance professionals should make certain that the attestation process is carefully monitored and that the attesting professionals are well informed as to the significant legal implications associated therewith.

A main component of internal auditing should involve tracking potential overpayments. The organization's compliance professionals should play a pivotal role in determining how the hospital will define and pursue the "identification" of overpayments per the FCA statute.[279] As discussed, once a provider "identifies" an overpayment, a sixty-day clock begins to run against the provider to disclose and return the funds.[280] Moreover, CMS expects providers to be diligent in their overpayment monitoring, and to investigate with "all deliberate speed" once an overpayment has been identified.[281] As discussed in this article, the risks associated with reverse

2011), available at http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_lshc_OrganizingToDriveQuality_121211.pdf.

275. See Healthcare Reform Meets Hospital Operations: Healthcare Reform Roundtable, MORGAN LEWIS (June 29, 2010), available at http://www.morganlewis.com/pubs/Materials_HealthcareReformRoundtable_29-june-10.pdf.

276. See Section IVC.

277. See supra notes 178-80 (CMS has instructed providers who submit CQMs in order to satisfy EHR incentive program requirements to retain all primary and supporting documentation in paper and electronic formats, for at least six years, in preparation for audits).

278. See EVERYTHING HITECH, supra note 179 (although not required by CMS, recommending providers create copies of patient level detail to substantiate the accuracy and completeness of the data as to each measure).

279. See supra Section IVD.

280. See id.

281. See id.

false claims liability are particularly high for entities submitting quality data pursuant to a VBP program.[282]

In order to carry out the hospital's obligations with respect to overpayment monitoring, the compliance department should oversee the process of confirming and quantifying a suspected overpayment.[283] This process can be especially complicated and burdensome in the VBP context when the overpayment consists of an incentive payment based on the hospital's Total Performance Score that is believed to be compromised by false quality data associated with the underlying quality measure scores. An evaluation of the overpayment would involve a review of quality data over an entire performance period for each quality measure and all patient records comprising each measure as well.[284] Depending on the scope of the apparent inaccuracies, compliance professionals may be managing the review of substantial numbers of medical charts, billing records and clinical quality measures data, which may ultimately necessitate hiring an outside consultant.[285]

D. Back to the Compliance Basics: A Robust Compliance Program

Of utmost importance, the organization's compliance plan program must be robust and comprehensive. Before PPACA, hospital compliance programs were voluntary albeit highly encouraged. With the passage of PPACA in 2010, however, the Secretary of HHS gained authority to render compliance plans mandatory for hospitals, among other health care providers.[286] Specifically, the Act provides that health care providers must establish a comprehensive compliance program that contains certain "core elements" as a condition of enrollment in government programs.[287]

In late 2012, CMS issued the much-awaited guidance regarding exactly what components of a compliance program are now mandatory. CMS

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282. See id.

283. See, e.g., Chananie, supra note 198.

284. See id.

285. See id. (describing the responsibilities associated with evaluating an overpayment in the scenario of basic billing fraud).

286. See Patient Protection and Affordable Care Act, Pub. L. 111-148, §6401, 124 Stat. 119 (2010) (instructing HHS to impose deadlines for mandatory compliance program implementation for providers or supplier by industry category; as of the time of this writing, these deadlines had not been established, with the exception of Guidance as to Sponsors, which is discussed herein).

287. See id; see also U.S.C. § 1395cc(j)(8) ("[A] provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements. . .with respect to that provider or supplier and industry or category.").

issued Final Compliance Program Guidelines[288] applicable to Sponsors that confirms the core Compliance Plan elements referenced in PPACA. Although a final set of program guidelines has not yet been released as to hospitals, physician practices, or other health care providers, the Final Compliance Guidelines for Sponsors nonetheless emerges as an important indicator of what is to follow, and is certainly instructive for all health care providers.[289]

Through the guidelines, CMS has established that all Sponsors must implement an effective compliance program that incorporates the set of seven core requirements that HHS and OIG have consistently cited in existing guidance materials[290] as the basic elements for a sound compliance program.[291] Originally, these core requirements emerged in the U.S. Federal Sentencing Guidelines Manual which set forth the main elements of an effective compliance program and focus on an entity's commitment to ensuring legal compliance through the exercise of due diligence aimed at preventing, detecting, and correcting illegal and unethical behavior. [292]

These compliance plan elements include: establishment of written compliance policies and procedures; designation of a specific individual or individuals to monitor compliance (i.e., compliance officer and/or compliance committee); commitment to conducting formal training and education programs; development of internal system for communication of suspected compliance violations; commitment to auditing and monitoring to evaluate compliance and identify potential problematic areas; maintenance of disciplinary policies which are consistently enforced; and development of process for investigation of suspected violations and reporting to the government and law enforcement authorities when necessary.[293] It is

288. Ctrs. Medicare & Medicaid Servs., Prescription Drug Benefit Manual, Chapter 9 – Compliance Program Guidelines and Medicare Managed Care Manual, Chapter 21- Compliance Program Guidelines, available at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf. The content of both Chapters 9 and 21 is identical and applies equally to the MA and Part D Programs.

289. Nicolas C. Harbist & Angela M. Guarino, United States: Ready or Not? Final Program Guidelines have come, BLANK ROME LLP, Dec. 17, 2012, available at http://www.martindale.com/health-care-law/article_Blank-Rome-LLP_1644438.htm.

290. See, e.g., OIG Compliance Program for Individual and Small Group Physician Practices, 65 Fed. Reg. 59434 (Oct. 5, 2000); Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998); Ctrs. for Medicare & Medicaid Servs., Compliance Program Guidance for Medicare Fee-For-Service Contractors (Mar. 2005), available at http://www.cms.gov/Medicare/Medicare-Contracting/MedicareContractingReform/downloads/compliance.pdf.

291. Compliance Program Guidance, supra note 290. The seven core requirements set forth in sections 422.503(b)(4)(vi) and 423.504(b)(4)(vi) serve as the framework for the Final Program Guidelines for Sponsors.

292. See U.S. SENTENCING GUIDELINES MANUAL § 8B2.1 (2010).

293. See Vernisha Robinson et al., The Evolving Medicare Advantage and Part D

imperative that organizations undertake a rigorous internal audit process and review of their existing policies and procedures in order to address risk areas pertinent to their type of provider or supplier. A comprehensive compliance program should avail organizations of benefits such as reduced fines, reduced sentences or deferred prosecution in the event of criminal investigation or prosecution. Furthermore, beyond reducing the impact of a civil enforcement action, an effective compliance and ethics program demonstrates a commitment to ethics in internal and external business dealings, ensuring a high level of integrity and bolstering the organization's reputation in the community.[294]

Compliance Program Guidance, AM. HEALTH LAWYERS ASS'N (Oct. 2, 2012), available at http://www.healthlawyers.org/Events/Webinars/RoundtableDiscussions/2012/Documents/roundtable_discussion_slides_121002.pdf (identifying and discussing the seven core elements at length).

294. See, e.g., White Paper: The Seven Elements of an Effective Compliance and Ethics Program, COMPLIANCE 360, available at http://www.compliance360.com/downloads/case/Seven_Elements_of_Effective_Compliance_Programs.pdf.