**** Pre-Publication Draft****

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QUALITY FRAUD: GATHERING THE THREADS

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Accepted for publication in the Health Law Handbook, 2023 Edition. Alice G. Gosfield, Editor, © Thomson Reuters. A complete copy of the Health Law Handbook is available from Thomson Reuters by calling 1-800-328-4880 or online at www.legalsolutions.thomsonreuters.com

Quality Fraud: Gathering The Threads

Since at least the Anti-fraud and Abuse Amendments of 1977, in a variety of both sweeping and narrow promulgations, Congress has repeatedly given the government ever increasing authorities to punish fraud and abuse in healthcare. With the advent of the power of whistleblowers to bring cases otherwise potentially unknown to the enforcers, the world of fraud and abuse has been the subject of considerable literature, most of it focused around financial behaviors in the federal health care programs: false claims, kickbacks, violations of the Stark statute, upcoding and the like. Far less attention has been devoted to the authorities of the government to punish fraud and abuse sounding in poor quality performance, quality failures, improper quality reporting, with still other penalties based on the clinical performance of the providers who receive reimbursement from government programs.

Now that value-based payment programs have emerged, provider attention to quality performance is intrinsic to qualifying for payment. The point of these programs is to lower cost while improving quality results. They inherently entail some kind of measurement of quality to determine whether any payment will be made or in other instances how much payment is appropriate. Some programs are purely pay for reporting programs. In those instances, the issue is whether the reports of quality were, first, made, and then whether they were accurate. These programs have no focus on whether the performance reported met any standard. In still other instances, substantively failed quality performance can be the sole basis for exclusion from the federal programs.

This article examines potential risk bases for quality fraud across a variety of provider types, from conditions of participation to quality performance reporting to pay for performance programs, prior review for appropriateness of high end imaging ot he value-based enterprise regulations under Stark and anti-kickback. It considers what qualifies as quality fraud including waste, EMTALA violations, over and under-utilization and medical necessity, QIO review, false quality reporting and implied fasle claims post -*Escobar*. It presents the penalties for misbehaviors and then moves to present the guidance the government offers on point. It concludes with some practical suggestions to avoid trouble.

1.0 Potential Risk Bases

The point of this article is to differentiate the types of compliance, enforcement and risks that are founded on clinical misbehaviors or quality reporting from those that are based in financial or organizational behaviors.

1.1 *Conditions of Participation*

The most basic definitions of quality in Medicare are the conditions of participation (COPs) that providers must meet to be eligible to participate in the program.. They are the minimum conditions of entry for payment. These conditions of participation apply to

hospitals, skilled nursing facilities, home health agencies, and more.[1] CMS states that "These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries."[2] They include basic operational requirements including having medical staffs, governing bodies, medical records, nursing staffs, patient safety programs, utilization review programs, and much more with some variation depending on the types of providers at issue. Complying with the COPs is the threshold for entry into the program. Failing to maintain compliance means potential loss of the ability to participate in Medicare through termination of the participation agreement. This is different from being excluded (see below at 3.2), but is a type of enforcement that turns on failure to meet substantive conditions of operation. The bases for termination of the participation agreement include failure to meet conditions of participation, along with other resistant behaviors including failure to disclose information, failure to provide access to regulators and more.[3] (See below at 3.1)

Interestingly, there are no formal conditions of participation as such for physicians and non-physician practitioners. While they must enroll to be paid, and there are conditions on their enrollment, including licensure by the state in which they practice, they do not have ongoing conditions of participation per se. Still further, non-facilities paid under Part B, like durable medical equipment suppliers and independent diagnostic testing facilities do have baseline entry requirements they must meet in order to participate in the Medicare program.

1.2 Quality Performance Reporting

Virtually all the facilities paid by Medicare are now subject to quality reporting programs focused around their specific activities. These include ambulatory surgery centers[4], home health agencies[5], hospice[6], hospital inpatient[7] and outpatient reporting[8], inpatient

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[1] CMS lists the following as having conditions of participation and conditions of coverage: ambulatory Surgical Centers (ASCs); Community Mental Health Centers (CMHCs); Comprehensive Outpatient Rehabilitation Facilities (CORFs); Critical Access Hospitals (CAHs); End-Stage Renal Disease Facilities; Federally Qualified Health Centers; Home Health Agencies; Hospices; Hospitals; Hospital Swing Beds; Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID); Organ Procurement Organizations (OPOs); Portable X-Ray Suppliers; Programs for All-Inclusive Care for the Elderly Organizations (PACE); Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services; Psychiatric Hospitals Religious Nonmedical Health Care Institutions; Rural Health Clinics; Long Term Care Facilities; Transplant Centers https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs

[2] Id

[3] 42 CFR § 489.53

[4] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/asc-quality-reporting

[5] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/homehealthqualityinits

psychiatric facility reporting[9], inpatient rehabilitation facility reporting[10], long term care hospital reporting[11], prospective payment system-exempt cancer hospital quality reporting[12] and skilled nursing facility quality reporting.[13] All of these programs share the intent to 'give consumers quality of care information to help them make more informed decisions about their healthcare options. This includes providing consumers with data about 'quality measures that aim to assess and foster improvement in the quality of care provided.' The metrics for each type of facility vary and are updated periodically. How facilities comply with this initiative is another basis for potential liability.

The facility based programs are distinct from the physician and practitioner focused reporting programs, which also include Accountable Care Organizations (ACOs) which are neither facilities nor practitioners but typically include both. The Merit Incentive Payment System (MIPS) adopted for physicians and other eligible clinicians such as nurse practitioners and physicians' assistants, as well as ACOs, adjusts payment up or down depending on performance two years earlier.[14] Because the regulators do not have direct access to the medical records and other supporting data which document the clinical performance, the clinicians are expected to report their performance themselves. That

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[6] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospice-quality-reporting

[7] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalrhqdapu

[8] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/hospitalOutpatientQualityReportingProgram

[9] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/IPFQR

[10] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/irf-quality-reporting

[11] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/index

[12] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/PCHQR#:~:text=PPS%2DExempt%20Cancer%20Hospital%20Quality%20Reporting%20(PCHQR)%20Program,-What's%20the%20PCHQR&text=It%20is%20also%20intended%20to,facilities%20and%20type%20of%20care.

[13] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information

[14] https://qpp.cms.gov/about/qpp-overview. For more discussion of MIPS, see Gosfield, "Coping with Merging Streams: Legal Issues in Physician Compensation," HEALTH LAW HANDBOOK WestGroup (2022 ed) pp. 149-190

said, Part B claims are one potential source of data, depending on the metric at issue.[15] First launched in 2017[16], the program has evolved over time. The metrics have changed and been reweighted. There are a host of measures from which eligible clinicians may select those to report.

Most clinicians are mandated to participate in MIPS based on their tax identification number. Some can also participate through groups. Some may only participate in groups. Clinicians who participate in Alternative Payment Models (APM) need not report to MIPS. Clinicians with very low numbers of Medicare patients or very low volume Medicare payments need not participate. But because the reporting comes from the clinicians themselves, by federal regulation there is a program to engage in data validation and auditing of the reporting.[17] Interestingly, the MIPS program does not specify in explicit terms what documentation would support the reports being made. This creates an administrative quandary for practices that seek to be prepared for such audits. Unsurprisingly there are legions of consultants who tout their ability to assist in preparing to be audited on MIPS reporting.

1.3 Payment for Performance

MIPS is a reporting program which affects the amount of reimbursement the eligible clinicians and ACOs can receive based on their scores or data submitted. It is not a payment program per se, but it affects the amount of payment clinicians will receive. Similar to the advent of the other provider reporting programs described above that are agnostic about the actual performance they report, in other aspects of the Medicare system, providers are paid differentially based on their performance. Where payment can vary by performance, chicanery is always a possibility.

There are several programs which are not precisely relevant to our concerns here wherein the government can lower payments to providers for poor performance. These include the hospital-acquired condition reduction program[18] and the hospital readmission reduction program.[19] The first uses mostly chart-abstracted reporting, but the second relies on claims paid, as the basis to determine if hospital payment will be reduced for failure to lower the number of hospital-acquired conditions or early readmissions. If the basis for

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[15] https://qpp.cms.gov/mips/quality-requirements

[16] 11/4/2016 Federal Register https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm

[17] 42 CFR § 414.1390

[18] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program

[19] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program

the payment, namely the claim or the abstracted reports for the hospital-acquired condition program, is inaccurate, these claims would be subject to more or less standard false claims liability (see below at __). Several other programs are focused around improving performance more broadly in terms of value. These include the Hospital Value-Based Purchasing (VBP) Program[20], the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)[21], Home Health Value-Based Purchasing (HHVBP)[22], Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program[23] and the Nursing Home Quality Initiative[24]. Similarly, the Medicare Shared Savings Program[25] created the basis for new entities---accountable care organizations (ACOs)-- to share in the savings they generate for the program. Essentially these are payment programs which shift monies around from poor performers to better performers, reducing payment for poor quality and increasing it for better performance; but they rest primarily on claims submitted by the participants.

1.4 Prior Review for Appropriateness

A different kind of payment related program is the Appropriate Use Criteria (AUC) requirements that apply to the ordering of certain advanced and expensive diagnostic imaging services. Introduced by statute in 2014[26] here, the provider ordering the service must consult with a clinical decision support mechanism (CDSM) before ordering advanced diagnostic imaging[27]. Regulations establish the types of entities and how they might qualify to provide criteria to be consulted by physicians and what the applicable requirements are to qualify as a CDSM.[28] CMS is charged with identifying annually priority clinical areas of

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[20] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing

[21] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/esrdqip

[22] https://innovation.cms.gov/innovation-models/home-health-value-based-purchasing-model

[23] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page

[24] https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits

[25] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram?redirect=/sharedsavingsprogram/

[26] Sec 218(b), Protecting Access to Medicare Act (PAMA) PL 113-93 (2014)

[27] Defined as "diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and (ii) such other diagnostic imaging services, including services described in section 1848(b)(4)(B) (excluding X-ray, ultrasound, and fluoroscopy), as specified by the Secretary in consultation with physician specialty organizations and other stakeholders. 1834(e)(1)(B) of the Social Security Act; 42 U.S.C. 1395m€(1)(B)

[28] 42 CFR 414.94(c)

concern to be addressed by AUC.[29] The fundamental idea here is that prior to ordering expensive advanced diagnostic imaging, an ordering professional must consult AUC offered by a CDSM.[30] The ordering professional is given a unique identifier to indicate the consultation occurred.

The Medicare claim, submitted by the furnishing professional, must then report which CDSM the ordering professional consulted, whether the service ordered would or would not adhere to specified applicable AUC or whether the AUC consulted was not applicable to the service ordered.[31] Over time, practitioners whose ordering patterns are considered outliers will be subjected to prior authorization requirements.[32]

The program impacts all practitioners who order advanced diagnostic imaging services as well as practitioners and facilities that furnish those services including physician offices, hospital outpatient departments (including emergency departments), ambulatory surgery centers and independent diagnostic testing facilities whose claims are paid under the physician fee schedule, the hospital outpatient prospective payment system or the ambulatory surgical center payment system. ***[Check the timing given the PHE.]***

1.5 VBAs - VBEs

In the drive toward motivating the delivery system to produce more value, in 2020 a massive overhaul of the Stark regulatory exceptions and the OIG's safe harbors, both addressed arrangements that without protection would raise compliance issues under both statutes. The challenge was how to allow multiple providers who remained independent to come together and share financially in the rewards for producing better value. The Stark regulations, by the statutory restrictions that define them, focus on financial rewards to physicians[33]. The OIG regulations are far broader and address other types of participants in these programs, including physicians.[34]

As is always the case, because the Stark exceptions provide safe haven or the arrangement violates, where physicians are involved in these activities, any compliance analysis involving Medicare must start here. Both sets of regulations address increasing (or decreasing) levels of financial risk from no risk, to meaningful downside financial risk, to full financial risk. Strangely, they address them in reverse order. Stark begins with full financial risk The OIG begins with care coordination that does not require any financial

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[29] 42 CFR 414.94(e) and (g)

[30] 42 CFR 414.94(j)

[31] 42 CFR 414.94(k)

[32] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program

[33] 85 Fed Reg 77684 (Dec 2, 2020); 42 CFR §411.357(aa)

[34] 85 Fed Reg 77492 (Dec 2, 2020); 42 CFR§1001.952(ee)-(hh)

risk.. It is beyond the scope of this article to address the details and nuance of either regulatory scheme, but it is worth reviewing in broad strokes how these regulations can provide additional bases for liability for clinically driven performance.

The regulations address definitions of value-based activities, value-based arrangements (VBAs), value-based enterprises (VBEs), value-based purposes, value-based participants and target patient populations (TPP). All of these are in play to claim the protections that the regulations offer, in their three iterations regarding risk assumption. Failure to comply with the complex requirements, whether in structuring arrangements or in their operations, could lead to violations of either source statute, as well as false claims liability.

In considering 'quality fraud', this set of rules cannot be overlooked. The purpose of these rules is to instigate value-based activities and arrangements by their participants thereby creating value-based enterprises (VBE) that will produce improved care at lower cost for the target patient populations. In the absence of these rules, these financial interrelationships would be prohibited. To the extent the participants in the VBE will share financially in the outcomes of these efforts, they must do so in compliance with a highly detailed set of rules. The Stark prefatory discussion focused around physicians is 34 pages long.[35] The OIG prefatory discussion, ranging far more broadly, is more than 100 pages![36]

2.0 What are quality failures

2.1 Waste: The Health Affairs Study

In the context of developing value-based payment programs, there has been greater focus on the high cost and questionable value of the constellation of services American patients typically receive. A recent study on the role of clinical waste in excess US Heath Spending, forges a clear link between the high cost of American care and failures of delivery of various kinds.[37] "Clinical waste" is low value spending for undesirable health care services. In an Institute of Medicine study in 2010, six drivers of waste in health care were identified and some of them are clearly in the bailiwick of quality failures: these include failures of care delivery, failure of care coordination and overtreatment[38]. Failures of care delivery are defined as poor execution or lack of widespread adoption of known best care processes.[39]

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[35] See n. 33

[36] See n. 34

[37] "The Role Of Clinical Waste In Excess US Health Spending, " Health Affairs Research Brief, June 9, 2022.DOI: 10.1377/hpb20220506.432025

[38] The other three were pricing failures, administrative complexity and fraud and abuse. Institute of Medicine 2010. The Healthcare Imperative: Lowering Costs and Improving Outcomes: Workshop Series Summary. Washington, DC: The National Academies Press. https://doi.org/10.17226/1275

[39] Berwick, D.M. and Hackbarth, A.D. (2012) "Eliminating waste in US health care", Journal of the American Medical Association, 307, 1513-1515. http://dx.doi.org/10.1001/jama.2012.362

These include "doing the wrong thing" (errors and adverse events) and not doing the right thing. Failure of care coordination occurs when patients fall through the cracks of the fragmented care system. While difficult to define, like Potter Stewart's view of pornography, reviewers know it when they see it. By comparison with other countries the US is sadly lacking in widespread care coordination.

Overtreatment itself is a significant driver of wasteful spending, accounting for 2-8.4% of total health spending. This is remarkable given the many efforts going back to the earliest days of 'utilization review' in hospitals to try to curtail unnecessary lengths of stay. While length of stay may have declined the provision of unnecessary services with no benefit to patients is a persistent problem in the US. The characterization of this problem includes "overuse beyond evidence-established levels, discretionary us beyond benchmarks and unnecessary choice of higher-cost services."[40] The varieties of problems addressed in these studies are variably susceptible to attack using legal mechanisms as will be explored more fully below.

2.2 EMTALA

The Emergency Medical Treatment and Labor Act[41] (EMTALA) was enacted in 1986 to provide penalties for those hospitals and physicians who might transfer patients from an emergency room without stabilizing them first, particularly when they were in labor. Civil money penalties of up to $50,000 attach to failures to comply.[42] The penalties apply to physicians who sign certifications for transfer when the physician knows or should know that the benefits of transfer to another facility did not outweigh the risks of such a transfer, and who make misrepresentations concerning an individual's condition or other information, including the hospital's separate obligations under EMTALA. While the EMTALA statute and regulations call into question the clinical management of a patient, there is an entire body of caselaw reflecting the claims patients and the government have made under this law which go well beyond the boundaries of this article. That said, it is worth mentioning in the panoply of bases for government action based on quality failures, in this case, stabilization of the patient before transfer.

2.3 Under-, Over-utilization; Medical Necessity

Since 1972, the Medicare program has put a significant emphasis on avoiding 'over-utilization' which in the earliest years was predominately manifested in excessive hospital lengths of stay (LOS). When the law provided for the government to accept the surveys and accreditation of the Joint Commission for deemed qualification for Medicare participation,

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[40] See n. 35

[41] 42 USC §1395dd,Allo of the civil monetary penalties cited in this article are adjusted upward in accordance with the Consumer Price Index. See 87 Fed Reg 15100 (March 17, 2022). So, while the statute says the penalty would be up to $50,000 by adjustment for a hospital with fewer then 100 beds the penalty is $59,973 and for ahospital with more than 100 beds is $119,942.

[42] 42 CFR §1003.500

the one function that could not be delegated was utilization review – the internal processes of hospitals to monitor patient length of stay for appropriateness.[43] At the same time, specific bases for exclusion were added which included providing services substantially in excess of a patient's needs or of a quality that was substandard.[44] That was when hospitals were compensated based on cost reports. There was no other specific mechanism to tamp the incentive to over-utilization other than the PSRO program which became the QIO program (see below at 2.4) When the Medicare program shifted to diagnosis related group (DRG) payment, with one payment available per admission regardless of the length of stay, unless the hospital incurred a cost outlier visit or LOS outlier which were medically appropriate, the financial incentive to the hospital shifted to underuse. Hospitals would maximize the impact of the fixed dollar amount they would receive by providing as little care as possible. Congress thereafter enacted provisions addressing failures to provide appropriate care. (See 3.3 below)

On the physician side of the street, as has been hammered on repeatedly, the fee for service reimbursement to physicians in Medicare incentivizes them to do more rather than less. Audits by the legions of reviewers, whether Medicare Administrative Contractors (MACs), Unified Program Integrity Contractors (formerly ZPICs) or the Recovery Audit Contractors (RACs)[45] are intended to deter misbehavior based on the risk of audit as well as act as a warning to physicians in their utilization practices. These agencies may also affirmatively recoup monies paid already, or, in the case of the MACs to suspend payment and/or impose pre-payment review on those suspected of being miscreants in this regard.

Medical necessity is an inherent requirement to qualify for payment for services under the Medicare program. Not only must they be medically necessary upon audit or review, the claim forms themselves have embedded in them the explicit statement made by the claiming entity in each and every claim, whether facility or physician, that the services provided were medically necessary. The audit operations of the federal contractors as well as the operation of the QIO program were intended to reinforce this requirement. But one of the most potent forces to corral misbehaviors here is the whistleblower bar which, with a single Google search, will completely load the screen with exhortations regarding the necessity of medical necessity for all claims and that its absence creates a false claim because of the explicit statement in the claim. Medical necessity is a clinically determined judgment that does not turn on COPs or other regulatory foundations. It finds its foundation in the science which says what health care is best suited to meet the clinical

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[43] See 42 USC§1395x(k)(1) for the statutory authority for deemed status, but also 42 U.S.C. § 1395bb (1988 & Supp. III 1991)) for the continuing requirement for utilization review which could not be deemed, before the Joint Commission adopted any such similar standard.

[44] See 3.2 below.

[45] For a review of the activities of all these agencies and how they function, including practical guidance for confronting their determinations, see, Wachler, Nucci and Trivax, "Medicare Auditors, Recent Reforms and Federal Court Jurisdiction to Seek Injunctive Relief," HEALTH LAW HANDGOOK (2020 Ed), Gosfeidl ed., WestGroup, pp. 311-332

needs of the patient. Services that are medically necessary are the right services at the right time for a specific patient. These reflect many of the quality concerns that provide the basis for fraud and abuse as this article considers.

That medical necessity is a profoundly essential aspect of Medicare claims submission can be seen in the many criminal convictions of physicians for billing for and often providing services that were not medically necessary. There are also convictions for physicians who certified other providers' services, such as home health, as medically necessary. (See 3.5 below) Submitting claims for medically unnecessary services has been the basis for exclusions from the federal programs[46] as well as for settlements with respect to civil money penalties.[47] Not limited to physicians alone, hospitals have also paid hefty settlements to resolve liability from unnecessary procedures and submitting claims for medically unnecessary services.[48]

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[46] Reviewing the government's enforcement website only for 2022 at least two exclusions are clearly for medically unnecessary services. See, "Stanley Carter and Brad Carter Agreed to Be Excluded for 5 Years for Paying Remuneration to Physicians and Submitting Claims for Medically Unnecessary and Upcoded Therapy´; https://oig.hhs.gov/fraud/enforcement/stanley-carter-and-brad-carter-agreed-to-be-excluded-for-5-years-for-paying-remuneration-to-physicians-and-submitting-claims-for-medically-unnecessary-and-upcoded-therapy/ ; and "Dr. Vinay Malviya and Vinay Malviya, MD, PC Agreed to Be Excluded for 3 Years for Causing the Submission of False Claims for Medically Unnecessary Services"; https://oig.hhs.gov/fraud/enforcement/dr-vinay-malviya-and-vinay-malviya-md-pc-agreed-to-be-excluded-for-3-years-for-causing-the-submission-of-false-claims-for-medically-unnecessary-services/

[47] "Western Maryland Physician And Pain Management Practice Group Agree To Pay $980,000 To Settle Federal False Claims Act Allegations Of Billing For Medically Unnecessary Urine Drug Tests" (Aug 5, 2022) https://www.healthleadersmedia.com/revenue-cycle/western-maryland-physician-and-pain-management-practice-group-agree-pay-980000-settle; and "Dr. Scot Richardson and Southern California Head Pain and Neurologic Institute Agreed to Pay $499,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Services that Were Not Rendered or Were Medically Unnecessary" (Oct 2022) https://oig.hhs.gov/fraud/enforcement/dr-scot-richardson-and-southern-california-head-pain-and-neurologic-institute-agreed-to-pay-499000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-services-that-were-not-rendered-or-were-medically-unnecessary/; and "Dr. Kenneth Martinez and Neurology and Pain Specialty Center Agreed to Pay $919,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Medically Unnecessary or Upcoded Services" (Aug 18, 2022) https://oig.hhs.gov/fraud/enforcement/dr-kenneth-martinez-and-neurology-and-pain-specialty-center-agreed-to-pay-919000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-medically-unnecessary-or-upcoded-services/

[48] "Providence Health & Services Agrees to Pay $22.7 Million to Resolve Liability From Medically Unnecessary Neurosurgery Procedures at Providence St. Mary's Medical Center" (April 12, 2022) https://oig.hhs.gov/fraud/enforcement/providence-health-services-agrees-to-pay-227-million-to-resolve-liability-from-medically-unnecessary-neurosurgery-procedures-at-providence-st-marys-medical-center/#:~:text=Walla%20Walla%2C%20WA%20%E2%80%93%20Providence%20Health,neurosurgery%20procedures%2C%20announced%20Vanessa%20R.; and "AMITA Health Mercy Medical Center and AMITA Health Saints Mary and Elizabeth Medical Center Agreed to Pay $6.2 Million for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Medically Unnecessary Services" (May 17, 2022) https://oig.hhs.gov/fraud/enforcement/amita-health-mercy-medical-center-and-amita-health-saints-mary-and-elizabeth-medical-center-agreed-to-pay-62-million-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-medically-unnecessary-

2.4 QIO Review

The Professional Standards Review Organization (PSROs) program was enacted as part of the 1972 Social Security Act amendments.[49] It's purpose was to review Medicare services in accordance with norms, criteria and standards, to determine if they were consistent with professionally recognized standards of care, medically necessary, and in some cases impossible to be provided more economically in a different type of facility (e.g., a nursing home as opposed to a hospital). These were to be physician organizations engaged in peer review of other physicians. There were initially 54 of them.[50] They have, by statute, the authority to review care, access records, deny payment and in instances of gross and flagrant quality of care violations recommend to the OIG exclusion from Medicare. These violations are defined as follows:

> *a violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or places the program patient unnecessarily in high-risk situations.* [51]

Their authority entails ongoing quality review as well as reviews generated by beneficiary complaints or referrals from MACs or other auditors.[52]

Despite the continuing statutory and regulatory authorities, the Secretary of DHHS in the mid 2000s by fiat and by its own admission recharacterized the entire program as an ongoing quality review program engaging multiple stakeholders in two types of QIOs: (1) beneficiary and family centered patient care review which responds to all beneficiary complaints including with respect to whether they should be discharged from the hospital; and (2) 14 quality innovation network QIOs which "bring Medicare beneficiaries, providers, and communities together in data-driven initiatives that increase patient safety, make communities healthier, better coordinate post-hospital care, and improve clinical

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services/#:~:text=Medically%20Unnecessary%20Services-,AMITA%20Health%20Mercy%20Medical%20Center%20and%20AMITA%20Health%20Saints%20Mary,Claims%20for%20Medically%20Unnecessary%20Services

[49] 42 USC §1320c et seq

[50] For an early contemporaneous review and analysis of the law and its implications see, Gosfield, *PSROs: The Law and The Health Consumer,* Ballinger Press, Cambridge *(1975)*

[51] 42 CFR §476.1.

[52] See 42 CFR §476.10. QIOs must have written agreements with the auditors regarding coordination of reviews.. 42 CFR §476.80

quality."[53] There is a Medicare manual dedicated to their activities.[54] The law requires that CMS make an annual report to Congress under the program, but the last report that is available is from 2018[55]; and it makes no mention of any sanction recommendations or payment impacts from QIO review. It focuses on the quality metrics the QIOs used in their review of patient care. CMS entered into new QIO contracts in 2019. One QIO, KePRO, which serves HHS Region 6, reported that in 2020 it had engaged in 926 quality of care reviews on a variety of bases, and confirmed 170 of them.[56] But it did not report whether it made any recommendations regarding exclusions. It may not have because the subject isn't even alluded to in the report.

Still, there has been no effort to alter the statutory and regulatory authorities which support the QIO program; so their payment authority and sanction authority (to impose civil money penalties and/or recommend exclusions) remains in place. There are no less than 8 separate authorities in the regulations which define the scope of the QIO reviews, plus two additional forms of review related to DRG validation[57]. Regulations require that every hospital in a QIO area must maintain an agreement with their local QIO.[58] The QIO's payment decisions are binding on payment agencies.[59] Because they can only recommend exclusions to the OIG, it is difficult to determine whether exclusions based on quality of care issues emanated from a QIO review; and there is no mechanism to assess how often or in what circumstances any QIO has made such a recommendation. In 2016 the Secretary modified their manual provisions to better coordinate their review with authorities under EMTALA.[60] Whether the QIOs will ever rebound as sanction recommending authorities is unknown; but the legal authority for them to do so remains in place.

2.5 False Quality Reporting

With the advent of all the quality reporting programs (see 1.2 above), facilities and physicians report on their quality performance, sometimes with a payment effect and sometimes with no direct payment effect. When those reports are inaccurate or misleading

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[53] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs

[54] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/qio110c09.pdf

50 https://www.hhs.gov/guidance/document/report-congress-administration-cost-and-impact-quality-improvement-organization-program-0

[56] https://edit.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/Annual-Report-to-Congress-QIO-Program-Fiscal-Year-2012.pdf

[57] 42 CFR §476.10(b) and (c)

[58] 42 CFR §476.78(a) et seq

[59] 42 CFR §476.86

[60] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R24QIO.pdf

the risk of false claims arises in association with the payment effects of the reporting. This is a new and burgeoning area for whistleblowers. In *US ex rel Janssen v. Lawrence Memorial Hospital*[61] the whistleblower had contended, among other things, that the hospital falsified patients' arrival times in order to increase its Medicare reimbursement under pay for reporting and pay for performance programs. The hospital was subject to the Inpatient Quality Reporting program, the Outpatient Quality Reporting program and the Hospital Value Based Purchasing program, all of which relied to varying degrees on measures that incorporated patients' arrival times. In the Inpatient program the hospital also separately submitted Data Accuracy and Completeness Acknowledgements on an annual basis, certifying that the data is in fact accurate and complete. The circuit court granted the hospital its motion for summary judgment.

The Court of Appeals noted that the evidence demonstrated that the hospital falsified certain patient arrival times and reported some inaccuracies through other programs. The original relator in the case reported the hospital to a hotline which, using a third party contractor, investigated the allegations, but the government declined to intervene and took no action to reduce any payment to the hospital. The Court of Appeals took up the issue of materiality in this post-*Escobar*[62]opinion. The court cited the three factors to consider where allegations of False Claims Act liability turn on noncompliance with regulatory or contractual provisions: (1) whether the government consistently refuses to pay similar claims in similar circumstances or continues to pay; (2) whether the noncompliance goes to "the very essence of the bargain" or is only minor or insubstantial; and (3) whether the government has expressly identified a provision as a condition of payment. Still, none of these factors alone would be dispositive. More determinative was the fact that the government had years before been apprised of the problem and continued to pay the claims, making the assertion of materiality baseless. The government had other mechanisms to address inaccurate reporting by the hospital, said the Court, citing 42 CFR §412.140 and §419.46 both of which incorporate validation programs to review data on a sample basis. Further, in examining where in the reporting and payment programs the arrival time measures were deployed, the court found they were not material, and still further, that the Data Accuracy and Completeness Acknowledgement were "boilerplate compliance documents as part of the complex Medicare regulatory system and fail to elevate potentially less-than-perfect compliance to FCA liability." The Court affirmed the motion for summary judgment.

In a different type of allegation, another case turned on whether the timing of physician signatures and whether they were obtained in face to face encounters could form the basis for a false claims allegation. The Sixth Circuit overturned the lower court's dismissal[63]

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[61] No. 19-3011, (10th Cir, Feb 7, 2020)

[62] *US ex rel Escobar v. Universal Health Services, 579 US 176 (2016)*

[63] *United States ex rel Prather v. Brookdale Senior Living Communities, Inc.*, 892 F.3d 822 (6th Cir. 2018), cert. denied, 2019 WL 1231774 (U.S. 2019)

finding that without the government's knowledge of the late certifications, the fact of the government's continued payment did not impact the materiality of the signatures which had been required specifically to prevent fraud. Two additional cases proceeded against complaints of immateriality where (1) allegations were that podiatry residents were not properly supervised and the program director falsified documents to assert they were[64]; or (2) whether laboratory services were the result of improper kickbacks, or, more relevant to our inquiries here, whether they were medically necessary.[65]

The materiality standard in *Escobar* changed the foundation for relator generated false claims. Although the standard is said to be high, it is not insurmountable. The *Lawrence Memorial Hospital* case did not find the falsified arrival times to be material, but in other programs such as MIPS and the hospital value-based purchasing program the quality reports are substantially more significant to payment effects. It is not hard to imagine the whistleblower plaintiffs' bar refining their arguments to fashion better argued false claims cases.

2.6 Implied False Claims Based on Quality Failures

Reporting and administrative obligations are different from the problem of failed clinical performance. One of the earliest of these cases was the settlement in *Tucker House*[66] where patients in a nursing home were found to have bed sores. Ordinarily these problems would be managed by a freeze on admissions, a survey by the state survey agency, the issuance of a plan of correction and follow up. Rather than take that route, James G. Sheehan, the Assistant US Attorney in the Eastern District of Pennsylvania, fashioned the matter as a false claims case, asserting that each claim by the facility for a day of service implied that they were feeding the patients in accordance with regulatory requirements. But the presence of the bed sores indicated otherwise, since malnutrition is a factor in developing bedsores. The settlement was for $600,000. That case was followed by a litany of similar cases and settlements, primarily but not exclusively against skilled nursing facilities.

Post *Escobar*, there is a real question as to the extent to which implied false claims for clinical quality failures remain viable. In *US. ex. rel Winter v. Gardens Regional Hospital*[51] the role of the physician's judgment as to medical necessity of the services was the central issue. The Ninth Circuit overturned the lower court opinion which had taken the position that physician judgment could not be the basis for a false claim because by its nature it is an opinion and therefore could

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[64] U.S. ex rel Gelman v. Donovan, 2017 WL 4280543 (E.D. N.Y. 2017).

[65] *U.S. v. Berkely Heartlab Inc*, 2017 WL 6015574 (D.S.C. 2017)

[66] For a deeper discussion of implied false claims, see Gosfield and Shay, *MEDICARE AND MEDICAID FRAUD AND ABUSE* (WestGroup) 2022, § 5:14

[51] *Winter ex rel. United States v. Gardens Regional Hospital and Medical Center, Inc.*, 953 F.3d 1108 (9th Cir. 2020), cert. denied, 141 S. Ct. 1380, 209 L. Ed. 2d 124 (2021).

not be objectively false. "Because medical necessity is a condition of payment, every Medicare claim includes an express or implied certification that treatment was medically necessary. Claims for unnecessary treatment are false claims."[52] While there are many cases considering the relative materiality of various regulatory requirements that apply to the claims submitted, cases that focus on *Tucker House*-type clinical quality failures have ebbed considerably post-*Escobar*. Services may not be medically necessary but as delivered they may have been rendered properly. *Tucker House* and its progeny[67] posit very different failures as the basis for their effects.

3.0 What are the penalties?

3.1 *Termination of Participation Agreement*

There are 18 separate bases for termination of a hospital's or other provider's or supplier's participation agreement.[68] Many sound in issues of failing to disclose information or failing to provide access to information. Two of them entail breaches of the conditions of participation (COPs) in the first place. (See 1.1. above) ACOs have separate regulations for the termination of their participation agreements.[69] Given that the COPs include performance or provision of services to assure patient safety and quality, loss of the participation agreement is one of the first risks a non-compliant provider or supplier faces. The government offers a 15 day notice period, notifying the public at the same time unless there is an immediate issue of patient jeopardy, in which case they can terminate on different notice bases.[70]

3.2 *Exclusions*[71]

Exclusions are either mandatory or permissive. The effect of an exclusion is that "Those that are excluded can receive no payment from Federal healthcare programs for any items or services they furnish, order, or prescribe."[72] The impact of an exclusion, therefore, does not rest solely on the excluded person, but on anyone receiving an order or prescription from them. Mandatory exclusions last for five years and are typically based on actions by

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[52] Id at 8 of the CV publication

[67] See citations at n 61 above.

[68] 42 CFR §498.53(a)

[69] 42 CFR §425.218

[70] 42 CFR §425.218(d)

[71] For a deeper discussion of exclusions and other administrative penalties in general see, Chapter 4 of Gosfield and Shay, MEDICARE AND MEDICAID FRAUD AND ABUSE, WestGroup, A Thomson Reuters company.

[72] OIG's Exclusion webpage: https://www.oig.hhs.gov/exclusions/index.asp

others. For example, conviction of a criminal offense related to the delivery of an item or good payable by Medicare or Medicaid is grounds for exclusion. Of greater significance to our consideration here is the second ground which includes conviction of a crime relating to neglect or abuse of patients in connection with the delivery of health care.[73] This is not limited to federal healthcare programs. The term "patient" is defined in OIG regulations to include "any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being *** whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided."[74] By far, the vast majority of individuals excluded under this provision are home care or skilled nursing aides.[75] Still, individual clinicians including physicians, podiatrists, dentists, pharmacists and counselors have been excluded under this provision, which by its terms requires a prior conviction as the basis for action. Aggravating circumstances may extend the exclusion beyond five years[76]; while mitigating circumstances may diminish the timeframe.

Permissive exclusions turn on other judgments rather than the actions of other enforcement authorities. While many of the bases for permissive exclusions, which are in the discretion of the OIG, turn on obstructive behavior or failure to disclose information, adopted in 1996 was a provision that provides for permissive exclusion where an individual or entity

> *Has furnished or caused to be furnished items of services to patients (whether or not eligible for benefits under title XVIII or under a State health care program) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care.*[77]

Note that the improper services need not be paid for either by Medicare or a State health care program. Exclusion under this provision must extend at least a year. Still further, the professional standards of care are defined as "Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a state."[78] The first part of the provision addresses charging substantially in excess of your usual charge, but the second provision is based on quality concerns as noted.

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[73] 42 USC §1320a-7(a)(2); 42 C.F.R. §1001.101(b).

[74] 42 CFR §1001.2

[75] https://www.oig.hhs.gov/exclusions/exclusions_list.asp

[76] 42 C.F.R. §1001.102.

[77] 42 USC §1320a-7(b)(6)(B)

[78] 42 CFR §1001.2

As noted above, the QIOs have the authority to recommend exclusions to the OIG and they may, in fact, have contributed to some of the exclusions the OIG reports on its ongoing exclusion list. There, of the more than 60 individuals excluded under the quality of care provision quoted above (§1128(b)(6) of the Social Security Act) fully one third of them are physicians, and then there are also podiatrists and dentists, Every single one of the more than twenty physicians excluded under the provision was excluded for a quality of care violation!!

Another basis for permissive exclusions is making false statements or misrepresentation of material facts. If such statements, or omission of a material fact, is made in any application, agreement, bid or contract to participate or enroll as a provider under a Federal health care program, such provider or supplier may be excluded.[79] Presumably this provision would be available to address improper reporting under the various reporting programs noted above.

3.3 Quality based CMPs

Yet another administrative tool for enforcement of quality concerns under the law are civil money penalties that turn on quality problems. These range from improper data behaviors to clinical decision-making regarding discharges.

A civil money penalty (CMP) of up to $20,000 may be imposed on anyone who "knowingly gives or causes to be given to any person, with respect to coverage under subchapter XVIII of inpatient hospital services subject to the provisions of section 1395ww of this title [the inpatient prospective payment system], information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision when to discharge such person or another individual from the hospital".[80] With the advent of the prospective payment system in a major shift from the former cost reporting methodology for hospital inpatient services payment, the hospital's financial incentives shifted to put patients at risk for under-service and early discharge, since the hospital would be paid the same amount regardless of the patient's length of stay.[81] To forestall against hospitals responding to this incentive the CMP was created.

Similarly, an additional CMP is available against hospitals or critical access hospitals of up to $5000 per patient, created during the same period, to apply to anyone who "knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals"[82] who are eligible for Medicare or Medicaid and are under the care of a physician. The physician receiving such payment is also subject to a $5000 civil money penalty for each patient with respect to

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[79] 42 USC §1320a-7(b)(16)

[80] 42 USC. §1320a-7a(a)(3). See n 42 supra regarding upward adjustments in penalties. This is now $33,641.

[81] Barring the application of an appropriate length of stay outlier for an unusual case.

[82] 42 USC §1320a-7a(b)(1), (2). See n 42, This is now $5606

which he received any payment under the provision. This provision was used at one time to prevent what were then referred to as "gainsharing" programs, where physicians might benefit financially from their containing costs incurred by hospitals. But despite the OIG's initial antipathy toward such programs, they have been approved in Advisory Opinions and can be created in a compliant manner.[83] It is also possible to link such programs to quality performance as well.

Harkening back to the recurring theme of medical necessity, there is a CMP to apply in light of "a pattern of medical or other items or services that a person knows or should know are not medically necessary".[84] This may emanate from QIO review or by the OIG on its own motion. The ability to assert the physician should know the services were not medically necessary opens the door to a broader range of potential claims. The penalty is up to $20,000 per instance.

With regard to the quality reporting programs, it is noteworthy that an omnibus provision with potentially enormous application sits in another CMP provided for anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program."[85] But the penalty is far higher at $100,000 per false statement.

CMPs are imposed through the operation of the OIG's administrative armamentarium, and are not available for whistleblower actions. This likely has something to do with the relative scarcity of their use, particularly by comparison with whistleblower False Claims Act cases. In its report to Congress for March 2021, the OIG collected $32 million in CMPs and OIG's investigative work led to $1.37 billion in expected investigative recoveries and 221 criminal actions. OIG also took civil actions, such as assessing monetary penalties, against 272 individuals and entities.[86] In contrast the Department of Justice reported $5.6 billion in False Claims Act recoveries for FY 2021.[87]

3.4 Quality based CIAs

Corporate Integrity Agreements (CIAs) are used as part of the settlement of some False Claims Act cases. These agreements impose obligations on the signers which mirror what

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[83] For a broader discussion of the developments regarding gainsharing programs, see Gosfield and Shay, *MEDICARE AND MEDICAID FRAUD AND ABUSE*, WestGroup (2022-2023 Ed) pp. 582-3

[84] 42 USC §1320a-7a(a)(1)(E)

[85] 42 USC §1320-7a(a)(8)

[86] OIG DHHS Semi_Annual Report to Congress, October 2020-March 2021, https://oig.hhs.gov/reports-and-publications/archives/semiannual/2021/2021-spring-sar.pdf

[87] DOJ Press Release, February 1, 2022 https://www.justice.gov/opa/pr/justice1, 2022-department-s-false-claims-act-settlements-and-judgments-exceed-56-billion-fiscal-year

the OIG has set forth in its model compliance guidances.[88] (See ___ below) Providers consent to the obligations in order to avoid exclusion from the programs.

The sophistication and breadth of the CIAs has grown over the years.[89] They now routinely impose oversight by an Independent Review Organization (IRO). The OIG"s own description of the contents of CIAs is set forth on their website. They state "*A comprehensive CIA typically lasts 5 years and includes requirements to:*

- *hire a compliance officer/appoint a compliance committee;*
- *develop written standards and policies;*
- *implement a comprehensive employee training program;*
- *retain an independent review organization to conduct annual reviews;*
- *establish a confidential disclosure program;*
- *restrict employment of ineligible persons;*
- *report overpayments, reportable events, and ongoing investigations/legal proceedings; and*
- *provide an implementation report and annual reports to OIG on the status of the entity's compliance activities.*[90]

In the context of quality of care CIAs, the rules are slightly different.

> *Under this type of CIA, OIG requires that the provider retain an entity with clinical expertise to perform quality-related reviews. For example, some CIAs require the provider to retain an independent quality monitor that will look at the entity's delivery of care and evaluate the provider's ability to prevent, detect, and respond to patient care problems. Other quality-of-care CIAs require the provider to retain a peer review consultant to evaluate the provider's peer review and medical credentialing systems. Agreements may also require the provider to retain a clinical expert to review the medical necessity and appropriateness of certain admissions and medical procedures.* [91]

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[88] For a deeper discussion of the model compliance guidances see Gosfield and Shay, *MEDICARE AND MEDICAID FRAUD AND ABUSE*) WestGroup (2022-2034 Ed), §1:23-1:35, pp, 86-105

[89] For a consideration of common issues in CIAs and practical tips in agreeing to one, see Laura Laemmle-Weidenfeld, "The Corporate Integrity Agreement: What It Is and How to Negotiate One Your Clients Can Live Under," Health Law Handbook, (2015 ed.) §§3:1 et seq.

[90] https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

[91] https://oig.hhs.gov/compliance/corporate-integrity-agreements/quality-of-care.asp

As of January 2018 there were 7 CIAs on this separate list. As of 2021 there were six quality of care CIAs, almost all of them with skilled nursing facilities.[92] Of the 5 quality of care CIAs in place as of November 2022, Universal Health Services, a behavioral health hospital company, entered into its agreement regarding medically unnecessary services (among other misbehaviors) in 2020.[93] Four additional quality of care CIAs involve long term care facilities and their requirements to assure appropriate staffing and quality of care delivered to their residents. In 2019, Vanguard Health Services and its 8 related companies entered into an agreement.[94] SpringGate Rehabilitation, another nursing facility, had a similar CIA it entered in 2018.[95] Health Services Management, a Texas long term care company, entered into its quality of care CIA in 2017; and it was still in effect as of this writing in November 2022[96]. Also in 2017, Andover SubAcute and Rehab Center entered its agreement.[97]

The CIAs all state the bases on which the government can determine they have been breached. The government has taken action against such entities going all the way back to 2002. Then, South Shore Hospital and Medical Center had entered into a 5 year CIA . The OIG asserted the Hospital had perpetuated a long history of violating the CIA beginning in 2003 when the OIG imposed a stipulated penalty of $50,000 against them for such breach. Apparently this failed to get the attention of the powers at the facility, and they didn't even bother to notify the OIG when the facility was sold to new owners. The facility was excluded in 2006 for, among other things, failing to implement IRO recommended changes in processes.[98] Today, there are more than 40 enforcement actions the OIG has posted regarding the failure of parties to CIAs to adhere to them.[99] Many involve the type of

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[92] See fn 78 at 111

[93] Press Release, Universal Health Services, Inc. And Related Entities To Pay $122 Million To Settle False Claims Act Allegations Relating To Medically Unnecessary Inpatient Behavioral Health Services And Illegal Kickbacks https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act

[94] See the CIA here:
https://oig.hhs.gov/fraud/cia/agreements/Vanguard_Healthcare_LLC_Vanguard_Healthcare_Services_LLC_Boulevard_Terrace_LLC_Glen_Oaks_LLC_Imperial_Gardens_Health_and_Rehabilitation_Vanguard_of_Manchester_%20LLC_Vanguard_Financial_Svcs_LLC_etal_01092019.pdf

[95]https://oig.hhs.gov/fraud/cia/agreements/Memphis_Operator_LLC_dba_Spring_Gate_Rehabilitation_and_Healthcare_Center_01262018.pdf

[96] https://oig.hhs.gov/fraud/cia/agreements/Health_Services_Management_Inc_09152017.pdf

[97]
https://oig.hhs.gov/fraud/cia/agreements/Andover_Subacute_and_Rehab_Center_Services_Two_Inc_05312017.pdf

[98] https://oig.hhs.gov/publications/docs/press/2005/120705release.pdf

[99] https://oig.hhs.gov/Fraud/enforcement/ciae/

stipulated penalties that South Shore ignored, while others entail a straight exclusion from federal programs.

3.5 Criminal Liability

As noted above (See 2.3 in the section addressing medical necessity), physicians have been convicted of false claims for submitting claims for medically unnecessary services. The risk of criminal violation has risen so much that in October 2017, Mag Mutual, a physician malpractice insurance company published an article they called "Lack of Medical Necessity and the Criminalization of Clinical Decision Making" citing to their readers 10 separate convictions involving medically unnecessary services which are also sometimes referred to as 'worthless services'.[100] "The defendants in these cases include long-term care, hospice, and home health providers; pain management specialists; behavioral health providers; cardiologists; dermatologists; ophthalmologists; and spinal surgeons.'[101] There are also settlements with hospitals based on billing for and allowing medically unnecessary services to be performed. Not only is there criminal exposure for the claims for the unnecessary services, there is also exposure for approving or certifying services of other providers as medically necessary, when they were not. A physician in Chicago was convicted on 2017, of certifying patients for home health services which were not medically necessary and for which they did not qualify.[102] Five years later another physician in Chicago was convicted of fraud charges as a result of authorizing percutaneous allergen tests knowing they were not medically necessary.[103] In fact, there may be many more such cases, but the government's website on enforcement actions lists the Press Releases and notices sent by the various US Attorney's Offices and other enforcement authorities, who take differing approaches to what they emphasize in the descriptions of their actions in their press releases.[104]

4.0 What Guidance Does The Government Offer?

4.1 Model Compliance Guidances

Given the expanding authorities of the government regarding fraud and abuse enforcement,, the OIG first published an actual model compliance plan for clinical

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[100] https://www.magmutual.com/learning/article/lack-medical-necessity-and-criminalization-clinical-decision-making/

[101] Id.

[102] Lee, "Feds Crack Down on Health Care Fraud," Chicago Medical Society http://www.cmsdocs.org/news/feds-crack-down-on-home-health-fraud

[103] US DOJ, Press Release, "Federal Jury Convicts Doctor on Fraud Charges for Approving Medically Unnecessary Tests" (February 11, 2020) https://www.justice.gov/usao-ndil/pr/federal-jury-convicts-doctor-fraud-charges-approving-medically-unnecessary-tests

[104] https://oig.hhs.gov/fraud/enforcement/

laboratories in 1997. By the next year, it abandoned that approach in favor of detailed guidance to sectors of the health care industry regarding what they should include in their own self developed compliance programs. The guidances should all be viewed as advocacy documents. For each industry sector addressed, the OIG makes a case for why a voluntary compliance program is a beneficial undertaking. By following the guidances, it has been the position of the OIG that the risk of enforcement by the government or becoming the target of a whistleblower would be significantly diminished. As advocacy documents, many of the guidances cites the 10 advantages to maintaining a compliance program.[105] These reference improving quality, but make no argument or assertions regarding how a compliance program can affect quality of care at all.

The first model compliance guidance was published for hospitals in 1998[106]. That document was then updated, but not supplanted, because it provided supplemental guidance in 2005.[107] In the 1998 guidance, the word "quality" appears only four times in the text and four more times in the footnotes. That said, the references to quality are generic and seen as potential second benefits from having a compliance savvy culture, but with little attention to what precisely any hospital ought to do. By contrast, the 2005 supplemental guidance has a section devoted specifically to 'substandard care'[108], a term which is not even present in the 1998 publication. To emphasize the power of the requirements to provide proper care, the OIG says with regard to the ability to exclude a hospital for delivering substandard care:

> *Significantly, neither knowledge nor intent is required for exclusion under this provision. The exclusion can be based upon unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary.*

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[105] Besides preventing false claims, the OIG cites other important potential benefits including the ability to: "• Concretely demonstrate to employees and the community at large the hospital's strong commitment to honest and responsible provider and corporate conduct; • Provide a more accurate view of employee and contractor behavior relating to fraud and abuse;• Identify and prevent criminal and unethical conduct;• Tailor a compliance program to a hospital's specific needs; • Improve the quality of patient care; • Create a centralized source for distributing information on health care statutes, regulations and other program directives related to fraud and abuse and related issues; • Develop a methodology that encourages employees to report potential problems; Develop procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, other health care professionals and consultants; • Initiate immediate and appropriate corrective action; and • Through early detection and reporting, minimize the loss to the Government from false claims, and thereby reduce the hospital's exposure to civil damages and penalties, criminal sanctions, and administrative remedies, such as program exclusion." From the original hospital compliance guidance 63 Fed. Reg. 8987 (Feb. 23, 1998) at 8988

[106] 63 Fed. Reg. 8987 (Feb. 23, 1998)

[107] 70 Fed. Reg. 4858 (Jan 31, 2005)

[108] Id at 4870-4871

In addition to emphasizing the need to comply with the Conditions of Participation, hospitals are admonished to continually measure their performance against comprehensive standards. Not limiting their focus to nursing care and ancillary services, hospitals are further directed to monitor quality of services through credentialing and peer review of medical care.

The compliance guidance for individual and small group physician practices was published in 2000 and has not been supplemented or revised since.[109] With the publication, the OIG restated the seven components of a good compliance program[110] which it has stated in all of the model compliance guidances, but then they went on to say

> *However, unlike other guidances issued by OIG, this guidance for physicians does not suggest that physician practices implement all seven components of a full scale compliance program. Instead, the guidance emphasizes a step by step approach to follow in developing and implementing a voluntary compliance program.*[111]

Unlike the approach in the hospital context, for physicians, the OIG directly and explicitly linked compliance with quality of care:

> *The OIG acknowledges that patient care is, and should be, the first priority of a physician practice. However, a practice's focus on patient care can be enhanced by the adoption of a voluntary compliance program. For example, the increased accuracy of documentation that may result from a compliance program will actually assist in enhancing patient care.....Physicians should view compliance programs as analogous to practicing preventive medicine for their practice.*[112]

Quality is further addressed there with the OIG's major emphasis on proper documentation and how that facilitates improved quality. Towards that end, the guidance suggests monitoring claims denial rates by comparison with other similar practices of the same specialty as well as monitoring coding and service distribution rates comparatively. The OIG does not say so, but this data is available under the Freedom of Information Act from the Medicare Administrative Contractors. Regarding the elements of a compliance program, the OIG suggests that the individual charged with this responsibility be assigned the task of "Establishing methods, such as periodic audits, to improve the practice's efficiency and quality of services, and to reduce the practice's vulnerability to fraud and

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[109] 65 Fed Reg 59434 (Oct 5, 2000)

[110] • Conducting internal monitoring and auditing; • Implementing compliance and practice standards; • Designating a compliance officer or contact; • Conducting appropriate training and education; • Responding appropriately to detected offenses and developing corrective action; • Developing open lines of communication; and • Enforcing disciplinary standards through well-publicized guidelines

[111] Id at 59434

[112] Id

abuse."[113] As to compliance training, for physician practices the OIG suggests that billing and coding compliance training need not be provided separately from other training and that "All in-service training and continuing education can integrate compliance issues, as well as other core values adopted by the practice, such as quality improvement and improved patient service, into their curriculum."[114]

The Skilled Nursing Facility (SNFs) guidance was supplemented in 2008[115] after its initial publication in 2000[116]. Here is where the major shift in attention to quality can be seen with the word itself – "quality" – appearing no less than 50+ times in the document. It is beyond the scope of this article to address all of the references to quality, but the OIG explicitly states a shift in attention from the 2000 publication to make quality of care a priority in SNFs. Indeed, it is the very first topic addressed with respect to the contents of a voluntary compliance program for this sector. Under the rubric of quality of care, the OIG addresses 1. Sufficient staffing; 2. Comprehensive Resident Care Plans; 3. Medication Management; 4. Appropriate Use of Psychotropic Medications; 5. Resident Safety with three sub-categories of attention. This goes well beyond the directives to physicians to document well. The point is the government's own statements of a shift in its priorities for this sector even as it had expanded its attention to quality of care and its enforcement under the fraud and abused laws in other ways. This is a clear manifestation of the real change to emphasize quality as an aspect of fraud enforcement.

4.2 Government Guidance to Health Care Governing Boards

Following on guidance the OIG with the American Health Lawyers Association originally issued to health care boards in 2003,[117] in 2015 the OIG joined with the Association of Healthcare Internal Auditors, the American Health Lawyers Association, and the Health Care Compliance Association to offer "Practical Guidance for Health Care Governing Boards on Compliance Oversight."[118] The principles stated there are broad and applicable in a wide variety of health care settings. The document cites a range of resources from the Federal Sentencing Guidelines to the OIG's own CIAs as well as its compliance guidances, including an emphasis on making the scale and scope of programs appropriate to the size

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[113] Id at 59442

[114] Id at 59443

[115] 76 Fed Reg 56832 (Sept 30, 2008)

[116] 65 Fed. Reg. 14289 (March 16, 2000)

[117] OIG and AHLA, Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors (2003); OIG and AHLA, An Integrated Approach to Corporate Compliance: A Resource for Health Care Organization Boards of Directors (2004); and OIG and AHLA, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007).

[118] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2006053221-hi-practicalguidanceforhealthcareboardsoncomplianceoversight.pdf

and complexity of the organization, quoting its own position on flexibility for physician practices in their model compliance guidance.

Among the five functions noted as essential to be addressed in developing compliance programs and assess their impact is the quality improvement function which promotes consistent, safe and high quality practices within health care organizations. "Quality improvement is critical to maintaining patient-centered care and helping the organization minimize risk of patient harm."[119] Going further with its quality-related suggestions, the Guidance suggests that the Board quality committee work with management to create the content of dashboards to identify and respond to risks and improvement of quality of care. With respect to identifying and auditing potential risk areas, the document calls out quality-related events for specific attention. Citing the increasing emphasis on quality throughout the industry, as well as in value-based payments and global payments for improving patient care, new challenges have arisen. The document notes that new payment models place increased pressure to conform to recommended quality guidelines and improve quality outcomes. In addressing how to encourage accountability and compliance, the Guidance explicitly notes that some companies have made their annual incentive programs contingent on satisfactorily meeting annual compliance goals, including those related to quality. "Others have instituted employee and executive compensation claw-back/recoupment provisions if compliance metrics are not met. Such approaches mirror Government trends."[120]

The real point of the Practical Guidance to any organization confronting the potential for compliance risks from quality performance is that the government has made it abundantly clear that such attention is essential to (1) having an effective approach to avoiding enforcement liability as well as (2) fulfilling the fiduciary responsibilities of a board member.

4.3 Other Implied Advice

As the government stated explicitly in its Practical Guidance, it sees it's CIAs, model compliance guidances, and even enforcement settlements as excellent direction to other providers as to how to avoid trouble. The VBA-VBE regulations set forth the proper way of establishing interrelationships among providers where money will change hands as a result of performance. As noted previously, while the regulations are safe harbors for the OIG, meaning failure to comply with them does not mean the participants are violating the law; they are mandates under the Stark regulations. If you do not comply with those regulations you are in violation of the rules. That view should drive how all health care organizations, but particularly hospitals, physician groups and SNFs, confront the compliance challenges from potential quality fraud.

5.0 What To Do

[119] Practical Guidance at 7. In fact, the pages are not numbered, although there is a Table of Contents which refers to page numbers that do not exist.
[120] Id at p. 14.

The act, here, of pulling together all of the quality-related threads for compliance, including the bases for potential liability, the penalties from misbehavior and the guidance the government states directly, ought to make it clear to all health care providers that encompassing quality issues explicitly in their compliance programs, and more to the point, in their actual operations, will be essential going forward. The fabric these threads create is one upon which a variety of risks can rest. While it is true that civil money penalties do not spawn whistleblowers and that *Escoabar* has truncated the liabilities for implied certifications as the basis for false claims, there is a well established qui tam whistleblowers' bar that is creative, focused and always looking for new occasions to bring cases. I expect them to find this relatively new field of opportunity as ripe for additional attention. With the spread of value-based payment which, by definition, entails some measurement of quality performance, both in the federal payment programs and commercial programs, the chance that providers will run afoul of the mandates and suggestions set forth here can only increase.

My guidance to my clients will be that they ought to incorporate continuing affirmative review of the sources of potential liability set forth here as part of their ongoing compliance efforts. I will remind them that medical necessity is both an over-arching principle in Medicare claim submission as well as foundational to the reimbursability and coverage of all Medicare services. I will suggest they document the implemlentation and integration of efforts directed at assuring and measuring quality performance to avoid risk formally as part of their compliance programs. Further, I will recommend that they standardize to the science as much as possible, throughout the depth and breadth of their operations, by relying on – and incorporating explicitly -- clinical practice guidelines and other evidence-based directions regarding clinical performance– in the roles of clinicians, in documentation, in fashioning team approaches to care. To do so, as has been demonstrated here, will both avoid quality-based compliance problems in the first place, and will offer a defense if the issue arises.