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BEYOND FACE TIME V. 2.0: THE OIG AWAKENS

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In the 2016 edition of the HEALTH LAW HANDBOOK[1], I wrote about the then newly burgeoning phenomenon of Medicare paying for activities physicians conducted away from face-to-face patient visits or procedures. The definition of a physician service has not changed from the inception of the Medicare program.

> "*A service may be considered to be a service where the physician either examines the patient or is able to visualize some aspect of the patient's condition without the interposition of a third party*". [2]

The second part of the statement is what permits radiologists to bill for interpretations of images when they might never have seen the patient at all. The same was and is true for pathologists reading laboratory specimens.

Without revisiting the development of the Medicare program from something dominated by an emphasis on procedures including surgeries, the advent of visit codes defined the world for the non-proceduralists.[3] But those physicians, and particularly primary care physicians, lamented that the work they did for patients extended outside the examination or consultation room. The initiation of value-based care – improved quality at contained costs – led, inevitably, to the need to better coordinate and integrate care, which typically did not require or involve the patient's presence. Paying both for physician interactions with peers as well as their management of the delivery of care during the times patients were not being seen, developed over time.

Today, new codes have been added to address these continuing and growing requirements for an improved delivery system, to be supported with additional payments. As delivering and billing for these services and codes have become more popular, the OIG has taken an interest. Costs have risen. Settlements have been entered into (as we will see), and the risks to physicians become more significant with increased Medicare outlays.

This article reviews these essential non-visit/non-procedure codes and their implications, addresses potential pitfalls that could lead to false claims or enforcement, and then

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[1] Gosfield, "Beyond Face Time: The Evolution of Medicare Fee For Service In a Value Driven World." HEALTH LAW HANDBOOK (2016 ed.) (WestGroup, pp 1-30)

[2] Medicare Benefit Policy Manual (MBPM) Ch. 15, §30A

[3] For a more detailed review of the history see n 1 at 1-4.

considers the way these codes and how they are published and used may be considered in light of the legal principles that apply post *Escobar* and *Allina.*[4]

1.0 Early Non-Face-Time Services - Chronologically

1.1 "Incident to"

From the inception of Medicare, the rules have permitted physicians to bill for services actually not rendered by them, let alone not in the presence of the patient. Consider the typical physician office in 1966: a single physician, with one support person who performed all support tasks from reception, to billing, to venipuncture, transcription, electrocardiograms and vital signs, among other things. If Medicare had been designed to pay only for the direct hands on services of physicians no one would have participated. So, subject to some conditions, physicians could bill for services rendered by these support personnel as if they had rendered them personally. This was established in the originating statute that Medicare would cover

> "services and supplies including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills."[5]

Interestingly, there has never been any modifier or other way to distinguish a claim for incident to services from a claim for a physician's personally performed service.

To qualify as compliant, there must be a physician service to which the non-physician services are an incidental although integral part[6]. The physician must establish the treatment plan to which the incident to services relate. The physician need not see the patient at each visit. There must be a physician on premises in the office suite and immediately available to assist at all times that incident to services are billed; but the rules allow any physician in the clinic to provide the requisite supervision. NPs, PAs, CNSs and nurse midwives (NPPS) can be billed incident to up to the full level of visit their licensure allows and other personnel may be billed incident to the NPPs if the NPPs bill on their own number for the initial service to which those services are incidental. Strangely, the regulators specified in the 2016 Medicare Physician fee Schedule that the claim must be submitted under the number of the supervising physician – the physician on premises,

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[4] Saee 3.0 infra

[5] 42 U.S.C. § 1395x(s)(2)(A)

[6] See 42 CFR 410.26 and Medicare Benefit Policy Manual (MBPM) Chptr 15 Sec 60

even if he has no treating relationship with the patient at all. The physician to whom the services are incidental must demonstrate continuing involvement in the patient's care, but there is no frequency of visits requirement anywhere in the incident to rules. Rather, the standard is "a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment".[7] There is no definition of a "course of treatment", either.

As to whose may be included as incident to services, in 2008, CMS established that services with their own benefit category, like laboratory and diagnostic services, could not be billed incident to.

> "only those services that do not have their own separate and independently listed benefit category may be billed as 'incident to' a physician service" and "[c]onsequently, diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests, all of which comprise a single benefit category under section 1861(2)(3) of the [Social Security Act], may not be billed as 'incident to' services." [8]

This is actually a misstatement which has finally been restated appropriately in the Manual.

> "Physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, clinical psychologists, clinical social workers, physical therapists and occupational therapists all have their own benefit categories and may provide services without direct physician supervision and bill directly for these services. When their services are provided as auxiliary personnel (see under direct physician supervision), they may be covered as incident to services, in which case the incident to requirements would apply. " [9]

Astonishingly, the rules permit one physician to be billed incident to another physician under the same rules that apply to a non-physician being billed incident to a physician. In 2001 in a tussle over billing for physical therapy, citing their regulation at 42 CFR §410.26(a)(1), which addressed who qualified as auxiliary personnel,[10] the regulators said

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[7] MBPM Chapter 15 Sec 60.1B.

[8] 72 Fed. Reg. 51012, at 51016

[9] MBPM Chptr 15, sec 60A

[10] "***Auxiliary personnel*** means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent

“We deliberately used the term ‘any individual’ so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant.” [11]

Going back to 2009, the OIG has raised concerns about “incident to” billing,[12] but the basic rules have not been modified. That trouble can arise here is manifested by at least four OIG settlements in 2024 alone based on failure to provide proper physician supervision as required by the incident to rules.[13] Yet another 2024 settlement turned on the absence of a physician’s initiating visit to establish a course of treatment or no change to a patient’s plan

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contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.” 42 CFR 410.26 a)(1)

[11] 66 Fed Reg 55268 (Nov 1, 2001)

[12] OIG work found vulnerabilities related to "incident to" services, such as that these services were frequently delivered by practitioners who lacked the required licenses, certifications, credentials, or training. See Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services (OEI-09-06-00430) Aug. 3, 2009

[13] Citizen Advocates Agreed to Pay $58,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Without Proper Supervision https://oig.hhs.gov/fraud/enforcement/citizen-advocates-agreed-to-pay-58000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-without-proper-supervision/; Dermatology Consultants Agreed to Pay $20,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Without Proper Supervision https://oig.hhs.gov/fraud/enforcement/dermatology-consultants-agreed-to-pay-20000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-without-proper-supervision/; Dr. Hammad Malik Agreed to Pay $123,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Without Proper Supervision https://oig.hhs.gov/fraud/enforcement/dr-hammad-malik-agreed-to-pay-123000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-without-proper-supervision/; Camden-Clark Physician Corporation and Parkersburg Cardiology Associates Agreed to Pay $155,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Without Proper Supervision https://oig.hhs.gov/fraud/enforcement/camden-clark-physician-corporation-and-parkersburg-cardiology-associates-agreed-to-pay-155000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-without-proper-supervision/

of care.[14] Still another settlement focused on the billing of PA services at the physician rate, when they did not meet incident to requirements.[15]

1.2 Care Plan Oversight

> "Care plan oversight (CPO) is the physician supervision of a patient receiving complex and/or multidisciplinary care as part of Medicare-covered services provided by a participating home health agency or Medicare approved hospice."[16]

Introduced for first use in 1995, it is restricted to care management for patients in home health care or hospice, and not skilled nursing care. The components of the service entail one physician per patient who may be paid for spending at least 30 minutes in a calendar month engaged in the following activities: 1. developing or revising care plans; 2. reviewing subsequent reports of patient status; 3. reviewing laboratory or other studies; 4. communicating with other healthcare professionals not employed in the practice who are involved in the patient's care; 5. integrating new information in the medical treatment plan; 6. adjusting medical therapy. Telephone calls with family can not be counted, nor may travel time, nor time telephoning prescriptions "unless the telephone conversation involves discussion of pharmaceutical therapies".

The billing physician must be the one who signed the home health or hospice plan of care and must have had a visit with the patient within the six months immediately preceding provision of the first CPO service. To substantiate the delivery of the service, documentation in medical records for these services must indicate: the physician spent 30 minutes or more for care planning activities that count; the specific service furnished, including date and length of time; support for the need for ongoing complex medical management; integration of new information; adjustments to therapy. The physician must submit records, if requested and Include reports, if referenced. As is always the case the

[14] Charlotte Gastroenterology & Hepatology Agreed to Pay $389,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Not Covered https://oig.hhs.gov/fraud/enforcement/charlotte-gastroenterology-hepatology-agreed-to-pay-389000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-not-covered/

[15] Dermatology and Laser Center of Charleston Agreed to Pay $426,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Claims for Incident-to Services Not Provided as Claimed https://oig.hhs.gov/fraud/enforcement/dermatology-and-laser-center-of-charleston-agreed-to-pay-426000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-incident-to-services-not-provided-as-claimed/

[16] Medicare Claims Processing Manual (MCPM) Chptr 14, Sec 180

services must qualify as a reasonable and necessary CPO service. "Physician reviewed report" without an actual report would not meet documentation needs."[17]

The enumeration of what does not qualify and cannot be counted is a virtual roadmap to potential problems in billing these codes. "Services ***not*** countable towards the 30 minutes' threshold that must be provided to bill for CPO are: Time associated with discussions with patient, his or her family or friends to adjust medication or treatment; Time spent by staff getting or filing charts; Time for travel; Physician's time spent telephoning conversation involves discussion of pharmaceutical therapies; Services included in E/M; Signing previous orders without reviewing orders prior; Informal consults with uninvolved physicians; Discussions with his/her nurse or any nurse phone calls with HHA or hospice; Hospital discharge (CPTs 99238 - 99239) or observation discharge (CPT 99217) work not counted.[18]

In fact, the OIG has paid some attention to CPO services. In 2004, the OIG reviewed claims for CPO paid during years 2001-2003 by National Heritage Insurance Company and found that 14 California physicians were overpaid $4,800 with the money to be recouped.[19] Much later, in 2016, as part of a Special Alert regarding physician relationships with HHA and hospice, CPO was called out as a problem area.

> "home-visiting physician companies upcoded patient visits (i.e., billed at a level higher than warranted) and billed for care plan oversight services that were not actually rendered. The government also alleged that the physicians falsely certified patients as confined to the home when they were not actually homebound. In OIG's experience, the physicians participating in these schemes typically were not the Medicare beneficiaries' primary care physicians, who often were unaware that their patients were receiving home health services. "[20]

Against this background of highly detailed requirements, exclusions from coverage, and past problems, it is not hard to speculate about potential bases for liabilities here including

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[17] Noridian Medicare Jurisdiction E, (Nov 22, 2024) https://med.noridianmedicare.com/web/jeb/topics/hhh

[18] Id

[19] OIG , "Review of Claims for Care Plan Oversight Services Paid More Than $150 by National Heritage Insurance Company for Calendar Years 2001 through 2003", (2005) https://oig.hhs.gov/reports/all/2005/review-of-claims-for-care-plan-oversight-services-paid-more-than-150-by-national-heritage-insurance-company-for-calendar-years-2001-through-2003/

[20] OIG , "Alert: Improper Arrangements and Conduct Involving Home Health Agencies and Physicians," (June 22, 2016) chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://oig.hhs.gov/documents/other-guidance/899/HHA__Alert2016.pdf

such issues as failing to document time spent, not rendering the full time required, failing to document interactions with other professionals and the physician billing for CPO was not the same physician who signed the plan of care.

1.3 Split/Shared Visits

Including split/shared visits in this consideration of non-face time services is slightly over-reaching, since part of the physician's service must be done face to-face, but not all of it. First introduced in Transmittal 1776 in 2002, it is a number I always remember because of the independence it gave to physicians in sharing work with their clinical team. Available only for use in the facility setting, it was like incident to in the office except more liberal because the physician and staff need not have been in the hospital at the same time. Over time the requirements have been refined, and in 2022, CMS announced new rules would go into effect for 2023, but there would be no enforcement until 2024.

The split/shared visit rules are codified at 42 CFR §415.140. They define these visits as follows:

> *Split (or shared) visit* means an evaluation and management (E/M) visit in the facility setting that is performed in part by both a physician and a nonphysician practitioner who are in the same group, in accordance with applicable law and regulations such that the service could be could be billed by either the physician or nonphysician practitioner if furnished independently by only one of them.[21]

Under this rule the meaning of 'substantive portion' becomes critical

> *Substantive portion* means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit, or a substantive part of the medical decision making except as otherwise provided in this paragraph. For critical care visits, substantive portion means more than half of the total time spent by the physician and nonphysician practitioner performing the split (or shared) visit.[22]

Non face-time can be included in the time calculation. This would include such services as preparing to see the patient, reviewing test results, or discussing the case with other providers.[23]

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[21] 42 CFR §415.140(a)

[22] Id

[23] Baklid-Kunz, "Compliance with Medicare's Updated 2024 split (or shared) visit policy," Compliance Today, (April 26, 2024) https://www.jdsupra.com/legalnews/compliance-with-medicare-s-updated-2024-8013709/

There are documentation rules regarding who performed the substantive portion, but both physician and practitioner must be identified in the record. Medical decision-making (MDM) includes establishing diagnoses, assessing the status of a condition, and/or selecting a management option. Unlike incident to services, though, these services require a modifier.[24] Because medical decision-making may be performed out of the presence of the patient, that can be considered non-face time. Four types of MDM are recognized: straightforward, low, moderate, and high. The distinctions turn on the following factors: (1) The number and complexity of problem(s) that are addressed during the encounter; (2) The amount and/or complexity of data to be reviewed and analyzed' (3) The risk of complications and/or morbidity or mortality of patient management. The AMA offers a grid [25] demonstrating the application of these rules. In terms of non-face time, though, determining who performed the bulk of the medical decision-making for shared visits can be metaphysical. Note that for critical care only time may be used to determine who may bill for the visit.

Reportedly, prior to the rules applicable in 2024 as noted above, most facilities chose to bill based on MDM.[26] Since only one of the two practitioners splitting the visit must see the patient, that can make sense in freeing physician time. That said, there have been OIG settlements based on improperly billed shared visits. Going back to 2018, an orthopedic hospital paid $414,000 in settlement of claims for services billed as split/shared which were not.[27] In 2021, TeamHealth, a physician staffing company, paid $48 million in settlement of a false claims suit that alleged, among other things, improper billing of split/shared visits.[28]

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[24] Id at (c)

[25] AMA, "Evaluation and Management (E/M) Services Guidelines" (2022) https://www.ama-assn.org/system/files/2023-e-m-descriptors-guidelines.pdf

[26] Kidd and Hammonds, "The Perceived Impact of the New Medicare Rules for Split/Shared visits: A Survey of Advanced Practice Administrators," Cureus, (June 22, 2023) 15 https://pubmed.ncbi.nlm.nih.gov/37363121/

[27] McBride Orthopedic Hospital Agreed to Pay $414,000 for Allegedly Violating the Civil Monetary Penalties Law by Submitting Upcoded Claims and Claims for Services Provided Without Proper Supervision (Nov 1, 2018) https://oig.hhs.gov/fraud/enforcement/mcbride-orthopedic-hospital-agreed-to-pay-414000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-upcoded-claims-and-claims-for-services-provided-without-proper-supervision/#:~:text=Without%20Proper%20Supervision-,McBride%20Orthopedic%20Hospital%20Agreed%20to%20Pay%20%24414%2C000%20for%20Allegedly%20Violating,Services%20Provided%20Without%20Proper%20Supervision

[28] United States of America, ex rel. Caleb Hernandez & Jason Whaley, Relators v. Team Health Holdings INC., Team Finance, L.L.C., Team Health INC., & Ameriteam Services, L.L.C., Case 2:16-cv-00432-JRG, (E.D. Tex. Nov. 12, 2018).

2.0 Today's Coordination of Care Codes

These codes typically get published with the Medicae Physician Fee Schedule (MPFS) so they are proposed, subject to comment and finalized. This is relevant to the application of *Allina,* discussed more fully below at 3.2.

2.1 Transitional Care Management

Transitional Care Management (TCM) services first became available for use in calendar year 2013, The purpose was to support patients transitioning from inpatient settings back to the community. The settings from which the patients must come are virtually all inpatient settings including also hospital outpatient observation or partial hospitalization , or partial hospitalization at a community health center.[29] The settings to which the patient must be transitioning include home, domiciliary settings, like a group home or boarding house, nursing facility (not a skilled nursing facility) or assisted living facility. Strangely the language used is that the 'community setting"…"could include those listed." [30]

TCM services include face-to-face and non-face-to-face services during the 29 days after the patient's discharge from the inpatient setting. To bill for TCM, the physician or "clinical staff" under direction of the physician (or NPP) must contact the patient or their caregiver by phone, email or face-to-face within 2 business days after the patient's discharge, Medicare Administrative Contractors (MACs) have emphasized that "the term 'direct contact' does not include the use of digital assistants such as chat bots, Siri or Alexa for the required interactive communication."[31] "Clinical staff" was a term originally set forth in the introduction to the CPT book, but it has been adopted by CMS, as have the elements described in the CPT book for the two codes.

> "Clinical staff" means someone who's supervised by a physician or other qualified health care professional and is allowed by law, regulation, and facility policy to perform or assist in a specialized professional service but doesn't individually report that professional service."[32]

The description of the level of supervision is confounding. CMS states that since TCM codes are care management codes, auxiliary personnel may assign them for TCM non-

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[29] MLN Booklet, "Transitional Care Management Services", MLN 908628 (July 2024)

[30] Id at 4.

[31] See Noridian "Transitional Care management (TCM) Direct Contact" (Jan 8, 2024)

[32] See note 28 at 5.

face-to-face services "under the general supervision of the physician or NPP subject to applicable state law, scope of practice, and the Medicare Physician Fee Schedule incident to rules and regulations."[33] But incident to rules require direct supervision! If the interactive contact fails to occur after 2 or more unsuccessful separate contact attempts, the code can still be reported if the attempts are documented in the patient's medical record and attempts continue to be made Under any circumstances the required face-to-face visit must occur within the required time frames. CPT 99495 that entails a moderate level of medical decision making, requires a face-to-face visit within 14 days of discharge,. CPT 99496 which entails a high level of medical decision=making requires a face-to-face visit within 7 calendar days of discharge. The face-to-face visit may not take place on the day of discharge.

It is the non-face-to-face services that compose the 'management' aspect of TCM. The physician and clinical staff must provide patients with medically reasonable and necessary non-face-to-face services within the 30 day TCM period. Again, CMS uses the term "may " to describe what physicians or NPPs are to do as non-face-to-face services:

- Review discharge information (for example, discharge summary or continuity-of-care documents)
- Review the patient's need for, or follow up on, diagnostic tests and treatments
- Interact with other health care professionals who may assume or reassume care of the patient's system-specific problems
- Educate the patient, family, guardian, or caregiver
- Establish or reestablish referrals and arrange needed community resources
- Help schedule required community providers and services follow-up[34]

That the term 'may' is precatory and not mandatory calls into question how many of the bullet points must be provided. The same issue arises where auxiliary personnel may provide these non-face-to-face TCM services under general supervision:

- Communicate with the patient
- Communicate with agencies and community service providers the patient uses
- Educate the patient, family, guardian, or caregiver to support self-management, independent living, and activities of daily living

[33] Id

[34] Id at 6

- Assess and support treatment adherence, including medication management
- Identify available community and health resources
- Help the patient and family access needed care and services

Medication reconciliation must be provided on or before the face-to-face visit. Only one physician or NPP may report TCM services for the 30 days, and they are reported once during the 30 days. Other management services may be provided and E/M visits (other than the required face-to-face visit) may be reported during the 30 days. TCM may not be billed within a global surgery period. Documentation must include patient discharge date, first interactive contact date, face-to-face visit days and the level of medical decision-making moderate or high.

In July 2021, the OIG conducted a review of transitional care management services payments in calendar year 2015 and 2016.[35] The primary problems identified were : multiple physicians billed for the same 30 day TCM service period; TCM services were billed by the same physician with restricted overlapping care management services (like care plan oversight and another 13 services)[36] during the same 30 day TCM period; TCM and restricted overlapping care management services claims were submitted on the same date for services rendered during the same 30 day TCM period. Most remarkably no system edits were available at the MAC to prevent and detect overpayments for TCM – purportedly this has been corrected.

While those are essentially system-based problems for which MACs should have screened claims, there are other ways to get into trouble billing TCM. Given the requirements for the services to be paid, it would seem the following are additional areas of potential risk: missing the two day time deadline for interactive contact; failing to document a face-to-face encounter timely; failing to conduct medication reconciliation before the face-to-face visit; and misstating complexity of the patient's condition. The intricacy of the multiple components will surely end up at issue with respect to materiality under *Escobar.*[37]

2.2 Chronic Care Management (CCM)

[35] OIG, "Medicare Payments for Transitional Care Management Services Generally Complied with Federal requirements, but Some Overpayments Were Made". (July 2021) A-07-17-05100 https://www.oversight.gov/report/HHSOIG/Medicare-Payments-Transitional-Care-Management-Services-Generally-Complied-Federal

[36] Id at 4

[37] See infra at 3.1.

The purpose of CCM (99490) is to pay physicians for interactions with other providers, patients and managing a care plan for patients with two or more chronic conditions. There is also Principal Care Management which provides CCM for patients with a single chronic condition or with multiple chronic conditions but focused on a single high-risk condition. (CPT 99424, 99425, 99426 and 99427) The regulators considered the CCM service to be so broadly applicable that when it was introduced in 2015, CMS estimated that 35 million Medicare patients would be eligible to receive CCM; but in the first year they received reimbursement requests for only 100,000. In a major shift over a few years, by 2022 this had increased so that 99490 was billed 4,590,000 times by 13,600 providers. The top specialties billing the codes were internal medicine, family practice, nurse practitioners, and cardiology although other specialists also bill CCM. Still, this appears to be a far cry from the volume of patients who could be receiving and the physicians who could be billing CCM.

CCM is billable once a month. It requires at least 20 minutes of clinical staff time, directed by a physician or other qualified health care professional per calendar month. It is applicable for patients with two or more chronic conditions expected to last at least 12 months or until the death of the patient. The conditions must place the patient at "significant risk of death, acute/exacerbation/decompensation or functional decline."[38] CMS identifies 22 conditions that qualify but they are not limited to those. The core of the service involves the development of a comprehensive care plan, established, implemented, revised or monitored by the physician's staff.[39]

Unlike with TCM (above) which formally adopts the CPT definition of 'clinical staff', for CCM, the regulators refer to the CPT book for its definition of 'clinical staff'.[40] There are no definitions in the CPT book. CMS does not provide a cite, a link or any guidance whatsoever. In fact, the relevant language is under the heading in the front matter of the CPT book "Instructions for Use of the CPT Codebook". The language is precisely the same as that quoted above for TCM. Non-clinical staff time may not be counted in the 20 minutes of time spent to qualify to bill the service. The physician practice may engage clinical staff through vendors as long as the "incident to" standards are met; but if records do not demonstrate oversight or clinical integration between a third party providing CCM and the billing practitioner, the service is not billable. Still further, the service is typically

[38] See MLN 909188 (May 2024)

[39] Id

[40] See, "Frequently Asked Questions about Practitioner Billing for Chronic Care Management Services (last updated 8/16/22) https://www.cms.gov/files/document/chronic-care-management-faqs.pdf

rendered under general supervision and "incident to" requires direct supervision. The code 99491 is a personally performed service of 30 minutes of time and cannot be billed as an "incident to" service.[41] It is, in limited circumstances permissible to provide CCM services to multiple beneficiaries at the same time or perform a single activity that will benefit multiple beneficiaries! They offer the example of clinical staff performing CCM services for thirty minutes that will benefit 3 beneficiaries, but the total time must be split among the three, so each would have only had ten minutes of services performed for them. This offers many opportunities to get this wrong!

CMS describes the services as extensive including structured recording of patient health information, maintaining comprehensive electronic care plans, managing care transitions and other care management services, coordinating and sharing patient health information promptly within and outside the practice. The service begins after a comprehensive evaluation and management visit, Annual Wellness Visit or Initial Preventive Physical Examination to the patient, all of which are separately billable from the CCM. The practitioner must discuss CCM with the patient at that visit. The codes are not billable until that discussion takes place and is documented. The patient must sign a consent before the service can be billed, informing the patient of the availability of CCM, a written agreement to receive the services with authorization for electronic communication with other treating practitioners and providers, along with how to revoke the consent; and it must inform the patient that only one practitioner can bill CCM in a month.

The care plan itself typically includes but is not limited to the following elements: problem list, expected outcomes and prognosis, measurable treatment goals, symptom management, planned interventions and identification of the individuals responsible for each, medication management, community/social services ordered, a description of how services of agencies and specialists outside the practice will be directed/coordinated and scheduled for periodic review and, when applicable, revision. The plan must be available 'at all times' electronically to anyone within the practice providing CCM services and because CCM is a form of coordinated care, the plan must be shared outside the practice as appropriate.

Access to care is a required element of the service. The billing practitioner must ensure 24/7 access to care management services providing the patient with a means "to make timely contact with health care practitioners in the practice" who have access to the patient's electronic care plan to address his or her urgent chronic care needs.[42] The

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[41] Id

[42] Id

requirements address internal practice staffing approaches with the notion that the practitioner must ensure continuity of care with a single, designated practitioner or member of the care team with whom the patient is able to get successive routine appointments. The billing practitioner must provide enhanced opportunities for the patient and any caregiver to communicate with the practitioner through telephone, secure messaging, secure internet or other asynchronous non face-to-face consultation methods.

The care management services themselves entail the following: systematic assessment of the patient's medical, functional and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions and oversight of patient self-management of medications; managing care transitions between and among health care providers and settings including referrals to other providers, which is why a practitioner cannot bill CCM with TCM services, since they are redundant. As soon as the 20 minutes have been documented the code can be billed but the entire CCM service must be rendered. No visits can be included in the time since this code is explicitly for non-face-to-face services.[43]

Against this background, commentators have explored the reasons for the tepid uptake of billing for CCM. The difficulty and novelty of documenting time of staff spent outside of the office is cited, along with the other documentation requirements. The advent of third party companies to provide outsourced services is noted as well. Physicians have decried the 'racket' of for profit companies entering this arena and that outsourced nurses lack familiarity with the patients. Even in practices which have adopted CCM, a significant

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[43] In 2021, new codes were added: CPT codes 99487 – complex CCM, first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month -CPT code 99489 – add-on code for CPT code 99487; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month

CPT code 99490 (not new) – CCM services, at least 20 minutes of clinical staff time directed by a physician or other qualified health professional, per calendar month -CPT code 99439 – add-on code for CPT code 99490; each additional 20 minutes of clinical staff time directed by physician or other qualified healthcare professional, per calendar month; note this code, which was adopted in the

CPT code 99491 – CCM services provided personally by a physician or other qualified health care professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month -CPT code 99437 – add-on code for CPT code 99491; each additional 30 minutes by a physician or other qualified health care professional, per calendar month

In 2024 the Fee Schedule added G3002 for chronic pain management, with G3003 for each additional 15 minutes.

minority of patients choose to participate. Some patients say they don't want the interactions which are required.[44]

Limited adoption of the code or not, settlements and an OIG report have been significant. In 2017 Smart Clinic agreed to pay $24,000 for violating the civil money penalty law for submitting claims for chronic care services that were either not provided or not provided as required by 99490.[45] Two years later the OIG found hundreds of thousands of dollars in overpayments for CCM services.[46] Problems included providers billed CCM more than once for the same beneficiary for the same service period; the same provider billed for noncomplex or complex CCM and overlapping care management service rendered to the same beneficiaries for the same service periods; and incremental complex CCM services billed along with complex CCM services. By 2024, the price of settlement with the Department of Justice was substantially higher. A chronic disease management provider paid $14.9 million for misbilling CCM, with the relator pocketing $2.8 million.[47] Other potential areas of risk include using non-clinical staff to perform services; using a non-conforming consent; using an unqualified electronic medical record; incomplete systematic assessment and services not medically necessary because the patient's condition is not sufficiently threatening.

2.3 Remote Physiologic Monitoring (also called remote patient monitoring)

Introduced with the 2019 Medicare Physician Fee Schedule, remote physiologic monitoring (RPM) is "a form of asynchronous telehealth using digital devices to collect and send patient data and clinical information to a provider."[48] A variety of devices may be used including scales, devices that report heart rate, measuring blood sugar, blood pressure sleep problems, breathing and fetal monitors connected to the provider but which the

[44] Galewitz and Hacker, "Medicare's push to improve chronic care attracts businesses, but not many doctors" (April 17, 2024) KFF Health News

[45] https://oig.hhs.gov/fraud/enforcement/smart-clinic-agreed-to-pay-24000-for-allegedly-violating-the-civil-monetary-penalties-law-by-submitting-claims-for-chronic-care-services-that-were-not-provided-as-claimed/

[46] OIG Report "Medicare Made Hundreds of Thousands of Dollars in overpayments for Chronic Care management Services" (Nov 2019) (A-0717-05101)

[47] https://www.justice.gov/opa/pr/chronic-disease-management-provider-pay-149m-resolve-alleged-false-claims

[48] https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-and-remote-patient-monitoring

patient uses themselves. It is characterized as a form of E/M service described by codes 99453, 99454, 99091, 99457, and 99458. There are three components to the services: education and setup; device supply; and treatment management itself. [49]

As initially published, to qualify for payment, virtual check-in services could only be reported when the billing practice had an established relationship with the patient. This is not limited to only rural settings or certain locations. Individual services need to be agreed to by the patient; however, practitioners may educate beneficiaries on the availability of the service prior to patient agreement. HCPCS code G2012 is a brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment. It includes 5-10 minutes of medical discussion. HCPCS code G2010 is a remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment. Virtual check-ins can be conducted with a broader range of communication methods, unlike Medicare telehealth visits, which require audio and visual capabilities for real-time communication.[50]

All of that remains essentially true; but a year later more detailed specifications for the service were published. Directly from a fact sheet regarding the final payment policy for calendar year 2021, the government offered the following:

- "We finalized that consent to receive RPM services may be obtained at the time that RPM services are furnished.
- We finalized that auxiliary personnel may provide services described by CPT codes 99453 and 99454 incident to the billing practitioner's services and under their supervision. Auxiliary personnel may include contracted employees.

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[49] For a deeper consideration of RPM, see Marting, "There's No Place Like Home: Evolution of Payment for Remote Patient Monitoring," HEALTH LAW HANDBOOK (2021 ed), WestGroup, A ThomsonReuters company, pp. 349-395

[50] MEDICARE TELEMEDICINE HEALTH CARE PROVIDER FACT SHEET (Mar 17, 2020) https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

- We clarified that the medical device supplied to a patient as part of RPM services must be a medical device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act, that the device must be reliable and valid, and that the data must be electronically (i.e., automatically) collected and transmitted rather than self-reported.
- We clarified that after the COVID-19 PHE ends, 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454.
- We clarified that only physicians and NPPs who are eligible to furnish E/M services may bill RPM services.
- We clarified that RPM services may be medically necessary for patients with acute conditions as well as patients with chronic conditions.
- We clarified that for CPT codes 99457 and 99458, an “interactive communication” is a conversation that occurs in real-time and includes synchronous, two-way interactions that can be enhanced with video or other kinds of data as described by HCPCS code G2012.
- We further clarified that the 20-minutes of time required to bill for the services of CPT codes 99457 and 99458 can include time for furnishing care management services as well as for the required interactive communication.”[51]

In November 2023, the OIG issued a fraud alert regarding remote patient monitoring and unscrupulous service providers (who aren’t recognized providers in Medicare) signing up patients who had no medical necessity for the service, among other issues[52]. The next year, calling for more oversight of RPM, the OIG noted that the number of enrollees who received RPM was more than 10 times higher from 2019-2022; payments were more than 20 times higher in 2022 than 2019.[53] Of the patients reviewed, 94% were treated for chronic conditions and 7% for acute conditions. More than half were treated for hypertension, followed by diabetes and sleep disorders, A full 43% did not receive all three components of the service, and 12% did not receive treatment management. The OIG

[51] Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2021 (Dec 1, 2020) https://www.cms.gov/newsroom/fact-sheets/final-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-1]

[52] https://oig.hhs.gov/fraud/consumer-alerts/consumer-alert-remote-monitoring/

[53] OIG, “Additional Oversight of Remote Patient Monitoring in Medicare in Needed” (Sept 2024) OEI-02-23-00260

found that Medicare lacks information about who ordered RPM or who delivered it. It can be provided "incident to' by staff but the OIG recommended the use of a modifier to designate 'incident to" services!!! How this recommendation, which seems beyond simplistic, was made recently only in the context of RPM is astonishing to me. In the 2025 Medicare Physician Fee Schedule more codes were added for RPM.[54]

2.4 Advanced Primary Care Management Services[55]

Newly available for use in 2025, Advanced Primary Care Management (APCM) services combine principal care management (like chronic care management but for single conditions), with TCM and CCM. It requires technology based communication services including virtual check-ins, remote evaluation of pre-recorded patient information and interprofessional consultations. It is available for billing by physicians and NPPs who are responsible for all of a patient's primary c are services, serve as the focal point for all of the patient's needed health care services, and the patient has consented. It is intended primarily for primary care specialists like general internists, family physicians, geriatric medicine physicians or pediatricians.

Clinical staff provides the services under the direction of a physician or other qualified health care professional who meets the criteria noted above. Unlike some of the other codes, APCM has no time specific requirements. The patient consent must include notice that only one provider can furnish APCM in a month and that they have the right to stop at any time. The consent must also address that cost sharing may apply. There is to be an initiating visit for new patients unless someone in the practice has seen the patient within the past 3 years and has provided another care management service (APCM, CCM or PCM) during the past year.

The service has many components of the other care management services but in totality seem more extensive. The billing clinician has to provide 24/7 access and continuity of care including 24/7 access for patients or their caregivers with urgent needs to contact him or another member of the care team with real-time access to the patient's medical information. The patient must be able to schedule successive routine appointments with a

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[54] For a plain language presentation of the changes see, PYA "Providing and Billing Medicare for Remote Patient Monitoring", Updated February 2025 https://www.pyapc.com/wp-content/uploads/2025/02/Providing-and-Billing-Medicare-for-RPM-PYA-020325.pdf

[55] https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-primary-care-management-services

designated member of the care team. The care must be delivered in "alternative ways" to traditional office visits, like home visits or expanded hours ,

Eight (!) additional components are required according to CMS's instructions to physicians, cited above:

- *Provide comprehensive care management*, including:
  - Systemic needs assessments (medical and psychosocial)
  - System-based approaches to ensure receipt of preventive services
  - Medication reconciliation, management, and oversight of self-management

- *Develop, implement, revise, and maintain an electronic patient-centered comprehensive care plan.*
  - The care plan must be available within and outside the billing practice, as appropriate, to individuals involved in the patient's care
  - Members of the care team must be able to routinely access and update the care plan
  - You must also give a copy of the care plan to the patient or caregiver

- *Coordinate care transitions between and among health care providers and settings, including*:
  - Referrals to other providers
  - Follow-up after an emergency department visit
  - Follow-up after discharge from a hospital, skilled nursing facility (SNF), or other health care facility

- *Coordination of care transitions must include*:
  - Timely exchange of electronic health information with other health care providers
  - Timely follow-up communication (direct contact, phone, or electronic) with the patient or caregiver within 7 days of discharge from an emergency department visit, hospital, SNF, or other health care facility, as clinically indicated

- *Coordinate practitioner, home-, and community-based care.* You must provide ongoing coordinating communication and documentation on the patient's psychosocial strengths, functional deficits, goals, preferences, and desired outcomes from practitioners, home- and community-based service providers, community-based social service providers, hospitals, SNFs, and others.

- *Provide enhanced communication opportunities*. You must:
  - Offer asynchronous, non-face-to-face consultation methods other than the phone, like secure messaging, email, internet, or a patient portal

    - Be able to conduct remote evaluation of pre-recorded patient information and provide interprofessional phone, internet, or electronic health record (EHR) referral services
    - Be able to use patient-initiated digital communications that require a clinical decision, like virtual check-ins, digital online assessment and management, and evaluation and management (E/M) visits (or e-visits)

- *Conduct patient population-level management***.** You must:
    - Analyze patient population data to identify gaps in care
    - Risk stratify the practice population based on defined diagnoses, claims, or other electronic data to identify and target services to patients

- *Measure and report performance***,** including assessment of primary care quality, total cost of care, and meaningful use of Certified EHR Technology (CEHRT). You can either:
    - Report the Value in Primary Care MIPS Value Pathway (MVP). You'll report performance starting in 2026 for CY 2025.
    - Participate in a Medicare Shared Savings Program Accountable Care Organization (ACO), Realizing Equity, Access, and Community Health (REACH) ACO, Making Care Primary model, or Primary Care First model.

That these services are characterized as "advanced" perhaps justifies the extensive demands stated. There are three levels of codes but the most payment available per month is $110.

- G0556:

APCM services for a patient with one chronic condition, with an approximate reimbursement rate of $15 per patient, per month.

- G0557:

APCM services for a patient with two or more chronic conditions, with an approximate reimbursement rate of $50 per patient, per month.

- G0558:

APCM services for a patient with two or more chronic conditions who are Qualified Medicare Beneficiaries (QMB), with an approximate reimbursement rate of $110 per patient, per month.

It is expected that clinical staff would do most of the work, so it is not a payment for physician services per se. We will have to see how popular it becomes. The pitfalls from a

compliance perspective are the same as those for TCM and CCM, with the one relief that there is no time requirement applied here. But we still have no way of knowing which of the myriad elements noted above would be considered material in submitting claims under these codes. This is a quandary that arises under several Supreme Court cases discussed more fully below.

3.0 Enforcement Risks Given Caselaw

As we have seen, the OIG has already entered settlements with providers for failure to meet the requirements associated with these non-face-to-face codes. The rules of the game are published in a variety of ways. Some are in the Federal Register but not in formal regulations, but as descriptions of changes in the Medicare Physician Fee Schedule. Much of the guidance is found in MedLearn Matters articles and FAQs published on the CMS website. There is caselaw, prior to *Escobar*[56] in which a variety of conditions and requirements imposed by the government for Medicare payment were held to not qualify as the basis for false claims liability. In *US ex rel. Landers v. Baptist Memorial Health Care Corporation*[57], the court held that conditions of participation, provided in federal regulations, were not conditions of payment and therefore false claims could not be based on their violation. Conditions of participation are published in regulations. The Medicare Carriers Manual was not. Therefore its provisions regarding physician supervision could not form the basis for false claims in another case.[58] Even physician supervision regulations published in the Federal Register could not be the predicate for false claims liability in *US ex rel. Hobbs v. MedQuest Associates Inc.*[59] The evaluation and management documentation guidelines were not conditions of payment either, thwarting false claims liability.[60] This is hardly an exhaustive list, but merely examples of how some courts have treated what can be considered as the basis for false claims liability. Three Supreme Court cases have added to the legal basis for and against liability under the False Claims Act for a

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

[57] 525 F. Supp. 2d 972 (WD Tenn 2007)

[58] *US ex rel. Swafford v. Borgess Medical Center, 9*8 F Supp. 2d 822 (WD Mich 2000) aff'd 24 Fed Appx 491 (6th Cir, 2001)

[59] 711 F 3d 707 (6th Cir 2013)

[60] *US ex rel. Troxler v. Warren Clinic Inc,* 2015 BL 353837, 10th Cir., No 14-5144, 10/28/15

range of issues associated with claims submission. I turn now to *Escobar, Allina* and *Loper Bright*.

3.1 Escobar[61]

The principal issue in this case turned on what implied certifications were made by the provider submitting a claim for payment with respect to how the services had been delivered. Here, a behavioral health hospital was accused of submitting false claims as a result of its using unlicensed staff to treat the plaintiffs' daughter. They argued that by submitting the claim, the hospital was making the implied certification that it complied with the applicable requirements, including using licensed personnel. The *Escobar* opinion was unanimous with both sides claiming victory. That alone manifests the lack of clarity in its results.

Prior to this case the distinction between conditions of coverage and conditions of payment had characterized why there was a Circuit split among the appeals courts. The Supreme Court declared a different standard: Liability under the Act could arise where two conditions were met: "[F]irst, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with *material* statutory, regulatory or contractual requirements makes these representations misleading half truths."[62] (Emphasis added) This made materiality a critical matter for an implied certification to be present.

For purposes of materiality, although the court looked to the definition of it in the FCA, it ended up indicating that courts should use a holistic approach, taking into account a number of factors: the label of the requirement (e.g., condition of coverage, condition of payment, other condition, etc) as relevant but not automatically dispositive; whether the violation is significant or minor or insubstantial; whether the violation goes to the essence

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[61] For a nice contemporaneous analysis of the significance of this case, see Diesenhaus, Ellsworth and Umhofer, "Is that claim false?: Implied false certification liability after *Escobar",* HEALTH LAW HANDBOOK (2017 ed) WestGroup, pp.1-34; in addition, every issue of the HEALTH LAW HANDBOOK since incudes an article on the fraud and abuser update for the year, all of which have tracked developments under this case. One of the most relevant was by Lin and Roth, "Materiality for Federal False Claims Act Purposes After *Escobar:* Why It Is Now More Important than Ever for Providers to Understand Reimbursement Authorities," HEALTH LAW HANDBOOK (2020 Ed), WestGroup)pp. 396-421. Finally, see also Gosfield and Shay, MEDICARE AND MEDICAID FRAUD AND ABUSE (WestGroup) updated annually at §5.14 tracks ensuing caselaw.

[62] *Escobar* at 2001.

of the bargain or is just ancillary; what actions the government has taken when it had actual knowledge of similar violations.

In thinking about the risks noted throughout this article with regard to the range of non-face-to-face services, the fact of settlements with the OIG and investigations by that office regarding various failures to meet requirements does not establish materiality under the *Escobar* standard, but those actions could be relevant. To the extent that government action regarding the same issues has occurred, the risks under *Escobar* would seem heightened. As suggested by Lin and Roth,[63] and as the entire basis for this article, the OIG's actions so far put a premium on knowing the details of the reimbursement rules and applying them to care delivery. As to the newest service, APCM, we can't yet know how many of the detailed requirements, not published in regulations, would be material.

3.2 Allina

Another Supreme Court case addressed issues potentially relevant to the types of publications that have established the non-face-to-face services. Incident to and split/shared visits have been published in formal regulations. Many of the other services are created by adopting them as part of the Medicare Physician Fee Schedule, but the extent of the descriptions of requirements associated with billing them are variable. Some discussion in the Federal Register can sometimes be found, but often the real content of these requirements are set forth in MedLearn Matters articles and FAQs published on the CMS website.

This raises the issue of whether and how this sub-regulatory guidance can form the basis for false claims liability. The seminal case on point is *Azar v Allina Health Services.*[64] There, DHHS promulgated a policy which it posted on a website. The publication not only changed a substantive rule, but did so retroactively. The court in a 7-1 opinion held that the Medicare statute requires that when a "substantive legal standard" is pronounced, it must be subject to publication of notice and a comment period before publishing final rules. Citing the Medicare Act's language to provide notice for any "rule, requirement or other statement of policy…that establishes or changes a substantive legal standard governing the payment for services"[65] … the Court distinguished it from the Administrative Procedures Act (APA's) definition which it found explicitly excluded statements of policy by

[63] See n. 61 supra

[64] 139 S. Ct, 1804 (2019

[65] 42 USC 1395hh(a)(2)

definition. The Court focused on the language in the Medicare Act which refers to the need for such notice in the face of a 'substantive legal standard' whereas the (APA) uses the term a "substantive rule." Commentators[66] view the Medicare standard as decidedly lower in terms of requiring notice and comment by comparison with the APA rules; meaning under the Medicare Act there would be more instances of required notice and comment than under the APA.

Later that year the Officer of General Counsel of DHHS weighed in with its view of the standard. In its "Statement of Impact of *Allina* On Medicare Payment Rules"[67] "The critical question is whether the enforcement action could be brought absent the guidance document." Are the code descriptions in the CPT book guidance if CMS adopts them? Is the Fee Schedule 'guidance' or a legal standard? The OGC went on to say, presciently, ""We do not interpret *Allina* as compelling CMS contractors to promulgate Local Coverage Determinations ("LCDs") using notice-and-comment rulemaking. The next year OGC issued an Advisory Opinion on implementing Allina.[68]

> "OGC interprets the phrase "substantive legal standard" in Section 1871(a)2) to mean any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or eligibility of individuals, entities or organizations to furnish or receive Medicare services or benefits, and sets forth a requirement not otherwise mandated by statute or regulation."

Half a year later the Ninth Circuit directly addressed the issue of whether local coverage determinations (LCD's) had to meet the Medicare Act's notice and comment requirements.[69] The court found that LCDs are not binding and explicitly distinguished how the Medicare Act would address them as opposed to national coverage determinations (NCDs). For those, the Act requires a separate and distinct notice and comment period (30 days for NCDs as opposed to 60 days for other publications). In that case the Medicare

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[66] For a nice consideration of these issues with considerable context see, Geilman, "Implications of Azar v. Allina Health Services on Rulemaking: How to Know When Notice and Comment is Required Under the Medicare Act", 36 BYU J. Pub. L. 157 (2022)

[67] (Oct 31, 2019) https://d1198w4twoqz7i.cloudfront.net/wp-content/uploads/2019/12/05141151/CMS-Memo_Impact-of-Allina-on-Medicare-Payment-Rules.pdf

[68] OGC Advisory Opinion 20-05 On Implementing *Allina* (December 3, 2020) chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.hhs.gov/sites/default/files/allina-ao.pdf

[69] *Agendia v Becerra* 2021 WL 3011982 (9th Cir. July 16, 2021)

Administrative Contractor (MAC) had denied reimbursement for molecular biology laboratory tests as not reasonable or necessary. The Court found that because "reasonable and necessary" were statutorily required conditions, the MAC's interpretation did not establish or change a substantive legal standard. But in applying that court's reasoning, the question arises as well as to whether the publication of covered codes in the Medicare Physician Fee Schedule, with none of the detail set forth in the MedLearn Matters and FAQ articles is sufficient to meet the national coverage determination standard, and more to the point for this article, could serve as the basis for a false claim or overpayment determination.[70] Still further, many of the code descriptions are published in the CPT book, a private and proprietary document to which the government refers. How much of what is stated as required to bill the non-face-to-face services that are not described in formal regulations can qualify to create false claims liability? The pre-*Escobar* cases noted in the opening to this section have not, to my knowledge, been over-turned. This brings us to the final confounding Supreme Court case.

3.3 Loper Bright

Unlike the previous two cases, this Supreme Court opinion is not about healthcare, but it has implications for all federal agencies. The fundamental issue at hand[71] was how much deference courts should give to agency interpretations of the statutes under which they issue regulations. Again, it arises under the APA and not the Medicare Act. But the analysis, over-turning forty years of precedent, is based on the Constitution and not so much on the APA statute. In over-ruling the *Chevron case,*[72] the Court made a number of sweeping statements that were contrary to decades of judicial construction. "Perhaps most fundamentally, *Chevron*'s presumption is misguided because agencies have no special competence in resolving statutory ambiguities."[73] But agencies interpret statutes in their rule-making every day. Going further (with a dance analogy particularly appealing to me) Justice Roberts continued.

> "Because *Chevron* in its original, two step form was so indeterminate and sweeping, we have instead been forced to clarify the doctrine again and again. Our attempts to

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[70] A further potential complication lurks in the position taken by Secretary Kennedy of HHS rescinding the long-standing (since 1971) position of the predecessor to HHS under the so-called Richardson waiver, to adhere to and go beyond the requirements of the APA in fostering public participation in agency decision-making . " Policy on Adhering to the Text of the Administrative Procedure Act**" (**March 3, 2025) https://www.federalregister.gov/documents/2025/03/03/2025-03300/policy-on-adhering-to-the-text-of-the-administrative-procedure-act But as Allina makes clear, Medicare is subject ot its own rules apart frm the APA on notice and comment..

[71] *Loper Bright Enterprises et al, v Raimondo,* 603 U.S. 369 (2024)

[72] *Chevron USA Inc v Natural Resources Defense Counsel*, 467 US 837 (1984)

[73] *Looper Bright* at 23.

> do so have only added to *Chevron's* unworkability, transforming the original two step into a dizzying breakdance."[74]

The opinion concludes

> "Courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority, as the APA requires. Careful attention to the judgment of the Executive Branch may help inform that inquiry. And when a particular statute delegates authority to an agency consistent with constitutional limits. Courts must respect the delegation, while ensuring that the agency acts within it. But courts need not and under the APA may not defer to an agency interpretation of the law simply because a statute is ambiguous." [75]

In confronting the potential problems in delivering, documenting and submitting claims for reimbursement of non-face-to-face services, CMS has made highly detailed interpretations of the components of services in sub-sub regulatory guidance. These services are not even included in the National Coverage Determinations Manual. Some of the services are described in the CPT book which certainly does not meet the notice and comment requirements of the Medicare Act. Still further the opinion does not address the Medicare Act itself.

While I find these three Supreme Court cases to be relevant to the potential for false claims liability for failure to comply with reimbursement rules, I do not find them to be helpful. None of the lines they purport to draw are bright. What conditions are material, whether sub-sub regulatory guidance may be relied upon to create liability for those who do not conform and whether CMS interpretations of the meaning of the services provided will be a predicate for liability is completely unclear to me. Whether the OIG acts proactively in this context or whistleblowers are the instigators of trouble, there is much yet to be determined in terms of exposure to liability under these rulings.

4.0 Conclusion

The advent and advancement of non-face-to-face services paid for by Medicare is certainly a potential boon to physicians. But lurking within the process of delivering and effectively documenting these services are pitfalls with possibly significant consequences. The OIG has already focused some attention here and, assuming the Office continues to be active in HHS under the Trump 2.0 administration, that effort will likely continue. Lawyers will want to proactively help their clients avoid trouble by focusing on compliance issues in this burgeoning sector of care delivery.

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[74] Id at 32

[75] Id at 35.