DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

May 24, 2021

Mr. Chad B. Walker
Winston & Strawn LLP
2121 Pearl Street, Suite 900
Dallas, TX 75201

Dear Mr. Walker:

On January 19, 2021, we received a petition you submitted on behalf of Quantum Plus, LLC, to the U.S. Department of Health and Human Services ("HHS" or "the Department") pursuant to the HHS Good Guidance Practices Regulation, 85 Fed. Reg. 78,770 (Dec. 7, 2020). *See also* 45 C.F.R. § 1.5(a)(1). Your petition, attached as Exhibit A, challenges the following sections of the Centers for Medicare & Medicaid Services' ("CMS") Medicare Claims Processing Manual (MCPM) (Pub. 100-04), Chapter 12:

- Section 30.6.1 Selection of Level of Evaluation and Management (E/M) Service, (Rev. 3315, Issued: 08-06-15, Effective: 01-01-16, Implementation: 01-04-16); B. Selection of Level of Evaluation and Management Service; SPLIT/SHARED E/M SERVICE
- Section 30.6.12 Critical Care Visits and Neonatal Intensive Care (Codes 99291 - 99292) (Rev. 2997, Issued: 07-25-14, Effective: Upon implementation of ICD-10; 01-01- 2012 - ASC X12, Implementation: 08-25-2014 - ASC X12; Upon Implementation of ICD-10), CRITICAL CARE SERVICES (CODES 99291-99292**)**.
- Section 30.6.13 Nursing Facility Services, (Rev. 2282, Issued: 08-26-11, Effective: 01-01-11, Implementation: 11-28-11); H. Split/Shared E/M Visit.

Your petition asserts that the identified manual sections impose obligations beyond those required by the terms of the applicable provisions of the Medicare statute and regulations regarding billing for split/shared E/M services and critical care services, and requests that CMS withdraw them.

If these manual provisions do no more than explain existing obligations, they would be permissible, because the Administrative Procedure Act (APA) exempts interpretive rules from notice-and-comment rulemaking requirements. *See, e.g., Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). However, if the manual provisions constitute a legislative rule—because they "affect[] individual rights and obligations"—then the APA requires CMS to use notice-and-comment rulemaking. *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). Similarly, if the requirements imposed by the manual provisions "establish[] or change[] a substantive legal standard governing . . . payment for [Medicare] services," then CMS is also bound to proceed only through regulation. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810 (2019) (interpreting Section 1871 of the Social Security Act ("the Act")).

The Department agrees that the manual provisions cited in the petition effectively impose certain binding obligations that are not reflected in duly enacted statutes or regulations lawfully promulgated under them, and CMS will take action to withdraw them. The Department agrees that the provisions of the MCPM cited in the petition impose certain requirements that are not reflected in the Medicare statute or regulations. Therefore, CMS anticipates addressing these issues through notice-and-comment rulemaking. Meanwhile, Current Procedural Terminology (CPT) guidance continues to apply for services billed and remain subject to the requirements of Medicare law and regulations.

In the absence of these manual provisions, claims involving E/M services performed in part by both a physician and non-physician practitioner, and claims relating to critical care services will remain subject to the requirements of Medicare law and duly promulgated regulations including the following:

- Sections 1861(s)(1) and 1861(s)(2)(A) of the Act, respectively, establish Medicare Part B benefit categories for physicians' services and "services and supplies [] furnished as an incident to a physicians' professional service [hereinafter, "incident to" services]." *See also* 42 C.F.R. § 410.20.
- Section 1861(s)(2)(K) of the Act establishes a Medicare Part B benefit category for services "which would be physicians' services [] if furnished by a physician (as defined in section 1861(r)(1))," and services furnished incident to those services, which are performed by a physician assistant under the supervision of a physician, or by a nurse practitioner or clinical nurse specialist working in collaboration with a physician. *See also* 42 C.F.R. §§ 410.74, 410.75, 410.76.
- Section 1833(a)(1)(N) of the Act provides that the payment amount for physicians' services as defined in section 1848(j)(3) of the Act is "80 percent of the payment basis determined under section 1848(a)(1) [the lesser of the actual charge or fee schedule amount under the Medicare physician fee schedule (PFS)]."
- Section 1833(a)(1)(O) of the Act provides that the payment amount for "services described in section 1861(s)(2)(K) (relating to services furnished by physicians assistants, nurse practitioners, or clinical nurse specialists)" is "80 percent of [] the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848." *See also* 42 C.F.R. §§ 414.52(d), 414.56(c).
- The regulation at 42 C.F.R. § 410.26 provides the conditions under which Medicare Part B payment is made for "incident to" services furnished by physicians and other practitioners.
- Section 1848(b)(1) of the Act requires the Secretary to establish, by regulation, fee schedules that establish payment amounts for all physicians' services furnished in all fee schedule areas for each year by November 1 of the preceding year; and that each such payment amount for a service is equal to the product of: 1) the resource-based relative value for the service, 2) the dollar-value conversion factor for the year, and 3) the geographic adjustment factor for the fee schedule area, determined in accordance with other provisions of section 1848 of the Act.
- The regulation at 45 C.F.R. §162.1002(c)(1) establishes as the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Pub. L. 104-191) standard medical data code sets the combination of the Healthcare Common Procedure Coding System

(HCPCS) maintained by and distributed by HHS, and the CPT codes maintained by the American Medical Association, for physicians' services and other health care services.

- Through annual notice-and-comment rulemaking to establish the PFS for the coming year, including in the CY 2021 PFS final rule (85 Fed. Reg. 84472-85377 (Dec. 28, 2020)), CMS adopts for purposes of PFS payment CPT or other HCPCS codes that describe each discrete physicians' service, and sets fee schedule amounts and other PFS payment policies for those services.
- In the CY 2020 PFS final rule (84 Fed. Reg. 62844-62860), CMS generally adopted the new CPT codes for office/outpatient E/M services, and the associated prefatory language and interpretive guidance framework for the codes, issued by the American Medical Association's CPT Editorial Panel (available at the following website: https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management). *See also* 85 Fed. Reg. 84549.

Despite withdrawing the manual provisions cited in the petition, CMS, nonetheless, may revisit the policy for determining payment for "split/shared" E/M services and critical care services in the future. Thank you for bringing this matter to the Department's attention.

Sincerely,

Elizabeth Richter
Acting Administrator

EXHIBIT A

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January 13, 2021

Via Electronic Mail and FedEx

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Re: Petition to Withdraw Guidance Documents for Non-Compliance with *Allina* and the Medicare Act

This Petition is submitted on behalf of Quantum Plus, LLC pursuant to the Good Guidance Practices regulation (45 C.F.R. Part I § 1.5), finalized on Dec. 3, 2020 and effective Jan. 6, 2021.[1]

Pursuant to Section 1.5 of the Good Guidance Practices regulation, Petitioner, Quantum Plus, LLC ("Quantum Plus") respectfully petitions the Department of Health and Human Services ("the Department") to withdraw certain Medicare Claims Processing Manual ("MCPM") provisions that impose binding obligations beyond what is required by the terms of any applicable statutes and/or regulations. In particular, Petitioners request that the Department withdraw the MCPM's provisions setting forth when a split/shared E/M service can be billed under the physician's billing number (Ch. 12, §§ 30.6.1(B), 30.6.13(H)) and the MCPM's provision for billing services using a critical care services CPT code (Ch. 12, § 30.6.12), as described below.

I. The Department's Standard for Determining Whether Sub-Regulatory Guidance Violates the Medicare Act as Construed by *Azar v. Allina Health Services*

On December 3, 2020, the Department finalized a regulation titled "Department of Health and Human Services Good Guidance Practices" ("Good Guidance Practices Regulation") that mandates that guidance documents should not impose obligations on regulated parties that are not already reflected in statutes or regulations. This policy accords with Executive Order 13891 and

[1] Because the regulation does not set forth any detailed procedural requirements for this Petition, Petitioner would respectfully request the opportunity to supplement its Petition with any additional required information.

existing CMS policy.[2] The Good Guidance Practices Regulation, together with these existing policies, gives effect to the notice-and-comment requirement of the Medicare Act as construed by the U.S. Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1808 (2019), as well as to the requirements of the Administrative Procedure Act.[3]

In *Allina*, the Supreme Court affirmed that under Section 1871 of the Social Security Act, any Medicare guidance that "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]" must go through notice-and-comment rulemaking. *Allina*, 139 S. Ct. at 1809, 1814 (citing 42 U.S.C. § 1395hh(a)(2)).

Under *Allina*, a substantive legal standard that was not the product of notice-and-comment rulemaking is invalid and unenforceable. *Id.* at 1809–10. Section 1.3 of the Good Guidance Practices regulation implements the requirements of *Allina* on behalf of HHS and provides that HHS guidance documents that were not the product of notice-and-comment rulemaking do not have the force and effect of law:

> (a) Guidance Documents.
>
> > (1) Under the Administrative Procedure Act, the Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute.
> >
> > (2) The Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable statute or regulation.
> >
> > (3) Each guidance document issued by the Department must:
> >
> > > (i) Identify itself as "guidance" (by using the term "guidance") and include the following language, unless the guidance is authorized by law to be binding: "The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law."

HHS Good Guidance Practices Regulation, 45 C.F.R. Part I § 1.3(a) (2020).

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[2] *See* Mem., Dep't of Health & Human Servs., Dep. Gen. Counsel & CMS Chief Legal Officer Kelly M. Cleary & Dep. Gen. Counsel Brenna E. Jenny, Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019) ("Cleary Memo").

[3] The Administrative Procedure Act (''APA''), 5 U.S.C. 551 *et seq.*, mandates that rules imposing new obligations on regulated parties must go through notice-and-comment rulemaking. *See* Good Guidance Practices Regulation, Final Rule, 85 Fed. Reg. 78770 (Dec. 3, 2020).

In conjunction with issuing the new regulation, on December 3, 2020, the HHS Office of General Counsel ("OGC") released an advisory opinion "on implementing *Allina.*" *See* Ex. A, Implementing *Allina,* Advisory Op. 20-05 (Dec. 3, 2020). The OGC advisory opinion sets forth HHS's Office of General Counsel's "current views" on the meaning of "substantive legal standard" under the Medicare Care Act:

> 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 3) sets forth a requirement not otherwise mandated by statute or regulation.

Id. at 1–2 (citing *Select Specialty Hosp.-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53 (D.D.C. 2019)).

Further, the opinion states that "**the critical question is whether the violation of the Medicare rule could be shown absent the guidance document.** If the answer is no, then the guidance document establishes a norm and, under *Allina*, is invalid unless issued through notice-and-comment rulemaking." *Id.* at 2 (emphasis added). Thus, OGC's advisory opinion provides the standard for determining whether a particular guidance document is invalid under *Allina*.

For the same reasons, the sub-regulatory documents violate the Administrative Procedures Act ("APA").[4] They constitute a legislative rule because they "affect[] individual rights and obligations," so the APA requires CMS to use notice-and-comment rulemaking. *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). They impose binding new obligations that are not reflected in duly enacted statutes or regulations lawfully promulgated under them.

II. The Medicare Claims Processing Manual ("MCPM") Provisions at Issue Are Invalid Under the Department and OGC Standard

The MCPM includes provisions that impose obligations beyond what is required by the terms of the Medicare Act regarding split/shared and critical care billing processes. Because CMS could not show violations of these sub-regulatory rules when reviewing claims absent these MCPM provisions, they are invalid under the Department's standard as set forth in the Good Guidance Practices Regulation and the OGC advisory opinion.

Quantum Plus is a regulated entity subject to the regulatory authority of the Department and CMS. The provisions at issue in this petition appear in MCPM Ch. 12, Section 30 – "Correct Coding Policy." The beginning of Section 30 states "[t]he following general coding policies

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[4] In this respect, the provisions at issue are similar to the guidance documents HHS invalidated in Good Guidance Petition Response 21-01 (Jan. 8, 2021), available at https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf

encompass coding principles that are to be applied in the review of Medicare claims." Thus, CMS and its contractors use these MCPM provisions in adjudicating whether Medicare claims submitted by Quantum Plus's providers or by thousands of other contracted Medicare Part B suppliers are appropriate.

Quantum Plus and other entities related to ultimate corporate parent TeamHealth Holdings, Inc. are parties to a False Claims Act lawsuit currently pending in the United States District Court for the Eastern District of Texas. *United States ex rel. Hernandez and Whaley v. TeamHealth Holdings, Inc., et al.*, 2:16-CV-00432-JRG (April 25, 2016). The lawsuit involves claims that rely upon the same provisions of the MCPM that are the subject of this petition, but that lawsuit is not the basis for Quantum Plus's standing to file this petition.[5]

A. Petitioner Requests the Withdrawal or Modification of Medicare Claims Processing Manual, Chapter 12 - Physicians/Nonphysician Practitioners §§ 30.6.1(B), 30.6.13(H).[6]

Split/shared evaluation and management (E/M) services are a patient encounter involving both a physician and a non-physician practitioner ("NPP"), such as a physician's assistant. Sections 30.6.1(B) and 30.6.13(H) of Chapter 12 of the MCPM together establish the rules CMS and its contractors use to make coverage and payment decisions regarding split/shared E/M services. CMS and its contractors rely on these MCPM provisions to determine when split/shared E/M services are appropriately billed under the physician's National Provider Identification ("NPI") number as opposed to the NPP's number. No statutes or regulations establish a rule for how to bill split/shared claims, so CMS can only show a violation with regard to a split/shared claim billed under the physician's NPI by relying on the MCPM provisions we are asking to have withdrawn.

CMS Pub. 100-4, MCPM Ch. 12 Section 30.6.1(B) provides as follows:

> **Office/Clinic Setting**
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> In the office/clinic setting when the physician performs the E/M service the service must be reported using the physician's UPIN/PIN. When an E/M service is a shared/split encounter between a physician and a non-physician practitioner (NP, PA, CNS or CNM),

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[5] *See* Good Guidance Practices Regulation, 45 C.F.R. § 1.5(a) ("Any interested party may petition the Department to withdraw or modify any particular guidance document."); *cf. id.*, 85 Fed. Reg. 78784, response to comment regarding qui tam relators using guidance inappropriately ("HHS suggests that in these circumstances, regulated parties file a petition with HHS seeking clarification as to the appropriate scope of the guidance document at issue.").

[6] *Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners §§ 30.6.1(B), 30.6.13(H)*, U.S. Dept. of Health & Human Services Guidance Portal (January 6, 2021), https://www.hhs.gov/guidance/document/claims-processing-manual-chapter-12-physiciansnonphysician-practitioners-0.

> the service is considered to have been performed "incident to" if the requirements for "incident to" are met and the patient is an established patient. If "incident to" requirements are not met for the shared/split E/M service, the service must be billed under the NPP's UPIN/PIN, and payment will be made at the appropriate physician fee schedule payment. Hospital Inpatient/Outpatient (On Campus or Off Campus)/Emergency Department Setting When a hospital inpatient/hospital outpatient (on campus-outpatient hospital or off campus outpatient hospital) or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician's or the NPP's UPIN/PIN number. However, if there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service by only reviewing the patient's medical record) then the service may only be billed under the NPP's UPIN/PIN. Payment will be made at the appropriate physician fee schedule rate based on the UPIN/PIN entered on the claim.
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> **Hospital Inpatient/Outpatient (On Campus or Off Campus)/Emergency Department Setting**
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> When a hospital inpatient/hospital outpatient (on campus-outpatient hospital or off campus outpatient hospital) or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician's or the NPP's UPIN/PIN number. However, if there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service by only reviewing the patient's medical record) then the service may only be billed under the NPP's UPIN/PIN. Payment will be made at the appropriate physician fee schedule rate based on the UPIN/PIN entered on the claim. …

CMS Pub. 100-4, MCPM Ch. 12 § 30.6.13(H) further defines a split/shared encounter as follows:

> A split/shared E/M visit is defined by Medicare Part B payment policy as a medically necessary encounter with a patient where the physician and a qualified NPP each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service. A substantive portion of an E/M visit involves all or some portion of the history, exam or medical decision making key components of an E/M service. The physician and the qualified NPP must be in the same group practice or be employed by the same employer. The split/shared E/M visit applies only to selected E/M visits and settings (i.e., hospital inpatient, hospital outpatient, hospital observation, emergency department, hospital discharge, office and non facility clinic visits, and prolonged visits associated with these E/M visit codes). The split/shared E/M policy does not apply to critical care services or procedures.

CMS Pub. 100-4, MCPM Ch. 12 § 30.6.13(H) (emphasis added).[7] CMS and its contractors rely on the MCPM split/shared provisions to determine the circumstances in which a provider is entitled to higher reimbursement under the physician's NPI, as opposed to a lower reimbursement under the NPP's NPI. Because the MCPM standards and criteria for split/shared encounters are not reflected in any existing statute or regulation, there is no valid basis for CMS's reliance on such provisions to impose binding obligations on parties for when to bill split/shared E/M services using the physician's NPI.

The Office of General Counsel's Advisory Opinion 20-05 also supports withdrawal of these split/shared provisions set forth in the MCPM. In particular, according to the OGC's standard, the MCPM provisions are invalid because they: (1) define binding parameters (i.e., the criteria for when to bill split/shared E/M services using the physician's NPI); (2) the parameters govern a legal obligation relating to the scope of payment by Medicare for services (i.e., when it is appropriate to bill split/shared EM services under the physician's NPI); and (3) the requirement is not otherwise mandated by statute or regulation. *See* Ex. A, Implementing *Allina,* Advisory Op. 20-05 (Dec. 3, 2020). In accord with this standard, the critical question according to OGC is "whether the violation of the Medicare rule could be shown absent the guidance document." *Id.* For E/M services involving both a physician and an NPP, CMS could not show that it would be a violation to bill under the physician's NPI absent the MCPM provisions. Therefore, under OGC's standard, the provisions establish a norm under *Allina* and are invalid because they were not issued through notice and comment rulemaking.

In summary, the MCPM split/shared provisions are sub-regulatory and impose obligations beyond what is required by the terms of statute or regulations. They are not the product of a formal notice and comment process, and therefore, are invalid under the Medicare Act, *Allina*, and the Administrative Procedure Act, and they violate CMS policies (e.g., the Cleary Memo). Accordingly, Petitioner urges the Department to withdraw the split/shared MCPM provisions pursuant to Section 1.5 of the Good Guidance Practices Regulation.

B. Petitioner Requests the Withdrawal of Medicare Claims Processing Manual, Chapter 12 - Critical Care Services § 30.6.12.[8]

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[7] Although 30.6.13 on its face applies to Nursing Facilities Services, CMS and its contractors apply this provision to services provided in other encounter locations. *See, e.g.*, Palmetto GBA Medicare Administrative Contractor ("MAC"), "Incident To and Split/Shared Services FAQ" (published Dec. 5, 2017), attached hereto as **Attachment A**, CGSMedicare MAC, "Split/Shared Visits in Inpatient Hospital or Emergency Visits" (published Nov. 22, 2013), attached hereto as **Attachment B**; First Coast, "Split and shared visits FAQ" (published Jan. 25, 2020), attached hereto as **Attachment C**; Novitas Notice of Review (Nov. 19, 2018), at 10, attached hereto as **Attachment D**.

[8] *Medicare Claims Processing Manual Chapter 12 - Physicians/Nonphysician Practitioners § 30.6.12*, U.S. Dept. of Health & Human Services Guidance Portal (January 6, 2021), https://www.hhs.gov/guidance/document/claims-processing-manual-chapter-12-physiciansnonphysician-practitioners-0.

The standards CMS and its contractors rely on to make coverage and payment decisions for critical care service CPT codes are set forth in Section 30.6.12 of Chapter 12 of the MCPM. As with the split/shared provisions, there are no existing statutes or regulations that define coverage and payment standards for services billed using critical care CPT codes. The MCPM, however, provides that critical care CPT codes are appropriate only when the following criteria for critical care services are met:

> Pay for services reported with CPT codes 99291 and 99292 when all the criteria for critical care and critical care services are met. Critical care is defined as the direct delivery by a physician(s) medical care for a critically ill or critically injured patient. A critical illness or injury acutely impairs one or more vital organ systems such that there is a high probability of imminent or life threatening deterioration in the patient's condition."
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> Critical care involves high complexity decision making to assess, manipulate, and support vital system functions(s) to treat single or multiple vital organ system failure and/or to prevent further life threatening deterioration of the patient's condition.
> …
>
> Providing medical care to a critically ill, injured, or post-operative patient qualifies as a critical care service only if both the illness or injury and the treatment being provided meet the above requirements.
>
> Critical care is usually, but not always, given in a critical care area such as a coronary care unit, intensive care unit, respiratory care unit, or the emergency department. However, payment may be made for critical care services provided in any location as long as the care provided meets the definition of critical care.

MCPM Ch. 12 § 30.6.12(A). CMS and its contractors rely on the MCPM critical care provision to determine when a provider is entitled to higher reimbursement using critical care CPT codes, as opposed to a lower level of reimbursement for E/M services using different CPT codes. Although statutes and regulations set forth the general requirement that Medicare will only provide reimbursement for reasonable and necessary services,[9] the Act and other regulations do not provide a standard or criteria for determining when it is appropriate for a provider to bill for critical care E/M services as opposed to a lower level, and the law and regulations do not provide a definition of "critical care services." Additionally, although a regulation adopts the CPT codes as the HHS standard to be used for billing (45 C.F.R. § 162.1002), no statute or regulation specifically adopts

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[9] *See* 42 U.S.C.A. § 1395y(a)(1)(A) (2020) (providing that Medicare generally will not pay for items or services unless the item or service was "reasonable and necessary" for the diagnosis or treatment of a patient); 42 C.F.R. § 411.15(k)(1) (providing that services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury are excluded from Medicare coverage).

the critical care definition and criteria contained in the MCPM. That definition and criteria is contained only in the MCPM. Adopting the CPT Codes as the official Medicare payment codes does not convert every requirement contained in the CPT manual into a binding regulation. Such a result would circumvent the requirements of the APA and the Medicare Act, in addition to the HHS and CMS policies described above. As a result, CMS cannot enforce the MCPM's critical care provision as a legally binding standard.

The Office of General Counsel's Advisory Opinion 20-05 also supports withdrawal of the provision set forth in the MCPM for using the critical care CPT codes. In particular, according to the OGC's standard, the critical care MCPM provision is invalid because it: (1) defines binding parameters (i.e., the criteria for using the critical care CPT codes); (2) the parameter governs a legal obligation relating to the scope of payment by Medicare for services (i.e., when the services can be billed using the critical care codes as opposed to a different code); and (3) the requirement is not otherwise mandated by statute or regulation. *See* Ex. A, Implementing *Allina,* Advisory Op. 20-05 (Dec. 3, 2020). In accord with this standard, the critical question according to OGC is "whether the violation of the Medicare rule could be shown absent the guidance document." *Id.* CMS could not show that it would be a violation to bill under a critical care CPT absent the MCPM provision. Therefore, under OGC's standard, the provision establishes a norm under *Allina* and is invalid because it was not issued through notice and comment rulemaking.

In summary, the MCPM critical care provision is sub-regulatory and imposes obligations beyond what is required by the terms of statute or regulation. It is not the product of a formal notice and comment process, and therefore, is invalid under the Medicare Act, *Allina*, and the APA, and it violates CMS policies (e.g., the Cleary Memo). Accordingly, Petitioners urge the Department to withdraw the critical care MCPM provision pursuant to Section 1.5 of the Good Guidance Practices Regulation.

C. A Federal District Court's Application of *Allina* to an Internet-Only Manual Provision

At least one federal district court has applied *Allina* to hold that a CMS Internet Only Manual provision like those challenged in this petition constitutes a "substantive legal standard" in violation of the Medicare Act. *See Polansky v. Exec. Health Res., Inc.,* 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019). *Polansky* considered whether the Medicare Benefit Policy Manual's ("MBPM") policy for billing inpatient services, known as the "24-hour rule," constituted a "substantive legal standard" that "trigger[ed] a requirement for notice and comment under the Medicare Act" in accordance with *Allina*. *Id*. at 933–34.

The court concluded that, because the policy at issue "determined entitlement to reimbursement" and "delineate[d] the circumstances in which a hospital is entitled to higher inpatient reimbursement," it was a "substantive legal standard" under the Medicare Act. *Id*. at 935. The 24-hour benchmark provision established a time-based standard for determining inpatient status for the purposes of seeking Medicare reimbursement: "The physician should use a 24-hour period as a benchmark, i.e., he or she should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." *Id.* at 932. If the 24-hour benchmark was not met, the provider could not make a claim for inpatient

services but instead could make a claim for another billing status, such as for outpatient observation services, which is typically reimbursed at a lower amount. *See id*.[10]

Similar to the MBPM provision invalidated under *Allina* in *Polansky*, CMS and its contractors rely on the MCPM provisions at issue here to determine provider entitlement to bill split/shared E/M services under the physician's NPI and to bill for services using critical care CPT codes. For split/shared encounters, if a provider does not meet the criteria set forth in Sections 30.6.1(B) and 30.6.13(H), the services must be billed under the non-physician practitioner's NPI at a lower reimbursement amount. Likewise, if a provider does not meet the critical care criteria set forth in Section 30.6.12(A), the provider must bill those services using another E/M code reimbursed at a lower amount. The MCPM provisions at issue here similarly constitute substantive legal standards under the Medicare Act and *Allina* and are invalid because they were not issued pursuant to the requisite notice-and-comment process.

For these reasons, Petitioner respectfully requests that the Department of Health and Human Services withdraw the above-referenced MCPM provisions for non-compliance with *Allina*, the Medicare Act, and the Administrative Procedure Act, pursuant to Section 1.5 of the Good Guidance Practices Regulation and Department policy.

Respectfully submitted,

Chad B. Walker

[10] In 2013 HHS issued the Two-Midnight regulation (42 CFR § 412.3), which obviated the need for replacing the MBPM provision invalidated in *Polansky* through notice and comment.