DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

January 8, 2021

Kathleen Waters
DaVita Inc.
2000 16th St.
Denver, CO 80202

Re: Good Guidance Petition Response 21-01

Ms. Waters,

On December 23, 2020, you submitted a petition on behalf of DaVita, Inc. to the 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 Centers for Medicare & Medicaid Services ("CMS") Transmittal 10368[1] and MLN Matters No. MM11871[2] and asserts that through these sub-regulatory documents, CMS is unlawfully requiring dialysis facilities to report dialysis treatment time on claims. The Department agrees and CMS will be amending CMS Transmittal 10368 and MLN Matters No. MM11871 to remove this requirement.

In CMS Transmittal 10368, CMS instructed its Medicare Administrative Contractors ("MACs") to implement a new Value Code D6, which reflects the total number of minutes of dialysis provided during the billing period. At the same time, CMS announced a new requirement for End-Stage Renal Disease ("ESRD") facilities: "ESRD facilities are required to report VC D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments." CMS Transmittal 10368 at 4. Shortly after making these contractor directions public, CMS issued an MLN Matters guidance document advising ESRD facilities of the new requirement to include treatment time on claims. *See* MLN Matters No. MM11871 at 1 ("PROVIDER ACTION NEEDED: This article informs you about . . . the new value code required for reporting minutes of dialysis provided during the billing period.").

CMS announced this requirement solely through sub-regulatory guidance.[3] If CMS

[1] Available at https://www.cms.gov/files/document/r10368otn.pdf.

[2] Available at https://www.cms.gov/files/document/mm11871.pdf.

[3] Although CMS previously solicited comments from the public on the collection of duration of treatment data, CMS stated that it would take these comments into account "for future rulemaking." 84 Fed. Reg. 60,648, 60,782 (Nov. 8, 2019). This is consistent with the Department's earlier commitment to members of the public that "before

Transmittal 10368 and MLN Matters No. MM11871 did no more than explain existing obligations, they would be permissible, because the Administrative Procedure Act ("APA") exempts interpretive rules from notice-and-comment rulemaking. *See, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). However, if these documents 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 requirement to submit dialysis time on claim forms "establishes or changes 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.*, 587 U.S. __, 139 S. Ct. 1804 (2019) (interpreting Social Security Act Section 1871).

These sub-regulatory documents are not interpretive rules; instead, they impose binding new obligations that are not reflected in duly enacted statutes or regulations lawfully promulgated under them. CMS regulations require dialysis facilities to "furnish data and information to CMS and at intervals as specified by the Secretary." 42 C.F.R. § 494.180(h). The data and information "must . . . [i]nclude but not be limited to—(i) Cost reports; (ii) ESRD administrative forms; (iii) Patient survival information; and (iv) Existing ESRD clinical performance measures, and any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary." *Id.* § 494.180(h)(3). Dialysis treatment time does not fall within these four specifically enumerated types of "data and information" that facilities are required to submit to CMS. Although one ESRD clinical performance measure in existence when this regulation was promulgated—adequacy of dialysis[4]—includes time as a component, CMS has never before required dialysis facilities to submit time in one-minute intervals. Furthermore, when the agency did collect time information, it did so only in 15-minute intervals and did not condition payment on this data reporting.

Nor can CMS justify imposing this new requirement through sub-regulatory guidance by relying on the regulation's statement that the data and information that dialysis facilities must submit "include, but [are] not . . . limited to," the four specified types. 42 C.F.R. § 494.180(h)(3). To the extent this regulation purports to authorize the Secretary, through sub-regulatory issuances, to require the submission of additional data or other information not listed in the regulation, it is invalid, as this would be an unlawful end-run around the notice-and-comment requirements of the APA and Social Security Act Section 1871.

CMS transmittals to MACs often contain directions to agency contractors that are not intended to alter the behavior of regulated entities, and thus are usually not guidance documents. In the case of CMS Transmittal 10368, the Department acknowledges the direction to contractors refers to binding new obligations on ESRD facilities that constitute a substantive rule or legal standards promulgated without notice and comment. CMS often releases MLN Matters articles to provide helpful interpretive statements for members of the public. In the case of the MLN Matters article No. MM11871, the Department agrees that the article lays out binding

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any changes to the electronic reporting requirements based on the CPMs [clinical performance measures] are enacted," HHS would "provide notice and an opportunity for comment in the Federal Register." 73 Fed. Reg. 20,370, 20,442 (Apr. 15, 2008).

[4] *See* 73 Fed. Reg. at 20,441.

requirements that are not found in existing statutes or regulations by requiring ESRD facilities to submit dialysis treatment time to CMS.

CMS will issue a correction for CMS Transmittal 10368 and modify MLN Matters No. MM 11871 to withdraw the required submission of time on dialysis. Nonetheless, these data do have clinical value, and CMS may explore collecting this information at a later time. If CMS wishes to impose mandatory time collection as a condition of Medicare payment in the future, it will only do so after engaging the public in notice-and-comment rulemaking. Thank you for bringing this matter to the Department's attention.

// Signed //
Robert Charrow
General Counsel

EXHIBIT A

DaVita Inc.
2000 16th Street
Denver, CO 80202

December 23, 2020

Brenna Jenny
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 713F
Washington, DC 20201

VIA EMAIL: Good.Guidance@hhs.gov

Re: Petition for Review of CMS Transmittal 10368 Requiring Machine Reported Dialysis Treatment Time on the 072X Bill Type (Dated Sept. 24, 2020)

Dear Ms. Jenny:

We are writing in regards to CMS Transmittal 10368, dated September 24, 2020, which was not made public until November 10, 2020, announcing a new requirement that dialysis providers include total number of minutes of a dialysis session on Medicare dialysis claims ("Time Transmittal") as a requirement for payment. In this petition,[1] we request that the Department withdraw the Time Transmittal, and the related MLN Matters Article,[2] on the grounds that (a) it creates additional legal obligations beyond what is required by the terms of the applicable statute and regulations, and as a result, its issuance violates the Administrative Procedure Act[3]; and (b) it establishes a "substantive legal standard" announcing new binding parameters governing payment under the End-Stage Renal Disease Prospective Payment System (ESRD PPS), and as a result, was promulgated in violation of the rulemaking requirements in Section 1871(a) of the Social Security Act.[4]

Per the Time Transmittal, ESRD facilities are required to collect, aggregate and report dialysis treatment time on claims,[5] and Medicare contractors are required to return claims that do not include this information.[6] We interpret this to mean that CMS is conditioning payment on dialysis facilities meeting this new reporting requirement. Put another way, it appears that CMS

[1] In our previous letter to the General Counsel and Administrator Verma, sent on December 18, 2020, we identified both policy and legal reasons supporting withdrawal of the Time Transmittal. Withdrawal of the guidance pursuant to this petition would resolve the procedural defects we raised in section II of the December 18, 2020 letter. DaVita reserves the right to object to the underlying policy, and will continue to engage with CMS should the agency pursue rulemaking.

[2] Centers for Medicare & Medicaid Services, Changes to the End Stage Renal Disease (ESRD) PRICER to Accept the New Outpatient Provider Specific File Supplemental Wage Index Fields, the Network Reduction Calculation and New Value Code for Time on Machine , MLN Matters No. MM11871 (Nov. 12, 2020).

[3] *See* Dept. of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770, 78,786 (Dec. 7, 2020) (codifying good guidance practices in regulation, including procedure to petition for review of guidance).

[4] *See Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019); Dept. of Health and Human Services, Office of the General Counsel, Advisory Op. No. 20-05 on Implementing *Allina* (Dec. 3, 2020).

[5] *CMS, supra note 2.*

[6] *Id. at 7.*

is imposing a requirement that changes the existing substantive legal standards governing Medicare payment for dialysis services. While CMS solicited comments from the public on developing and refining reporting options for composite rate costs, including the option of collecting duration of treatment data on claims forms, it did so as part of a request for information, indicating that it would use comments to inform future rulemaking.[7] CMS has not made any proposal to adopt any particular cost reporting strategy, nor has it finalized through regulation such a policy. Instead, CMS is inappropriately promulgating this new rule though guidance.

The Time Transmittal guidance cannot be considered merely an interpretation of existing statutes or regulations governing payment. Section 1833(e) of the Social Security Act authorizes the Secretary to condition Part B payments on a provider's furnishing "such information as may be necessary in order to determine the amount of Medicare payment due such provider."[8] Current regulatory conditions of payment require facilities to report data necessary for accurate payment. Facilities "must furnish to the intermediary or carrier sufficient information to determine whether payment is due and the amount of payment."[9] We are not aware of any conditions that would require a facility to collect and report on a claim for payment the time spent on dialysis, as we understand that information would not have bearing on the amount paid on the claim.

The Time Transmittal requires contractors to reject claims lacking value code D6, and, in effect, requires providers to collect data and report on value code D6 as a condition of payment. We believe that the obligations under the Time Transmittal could only be promulgated under a legislative rule and, therefore, is subject to notice and comment rulemaking requirements under section 553 of the Administrative Procedure Act. Furthermore, we believe that Section 1871 of the Social Security Act precludes CMS from implementing the new requirements until the requirement has been promulgated by regulation, after proper notice and an opportunity for public comment.[10]

We acknowledge that the conditions of coverage for ESRD facilities do include a requirement to report certain types of data, but note that the new Time Transmittal would materially expand reporting requirements and create new consequences (non-payment of claims) for failure to meet those requirements. CMS regulations at 42 C.F.R. § 494.180(h) require

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[7] *End-Stage Renal Disease Prospective Payment System, Final Rule*, 84 Fed. Reg. 60,648, 60,778-782 (Nov. 8, 2019).

[8] *42 U.S.C. § 1395l(e).*

[9] *42 C.F.R. § 424.5(a)(6).*

[10] *42 U.S.C. § 1395hh(a)(2) (requiring a 60-day comment period for "any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services"). See also Allina Health Servs. v. Price, 863 F.3d 937 (D.C. Cir. 2017) (holding that a policy commanding fiscal intermediaries to use certain values to calculate disproportionate share hospital payment adjustments was a requirement that changed existing standards governing payment for services, and therefore was subject to the notice and comment rulemaking requirements under Section 1871 of the Social Security Act), aff'd Azar v. Allina Health Srvs. 139 S. Ct. 1804 (2019).*

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electronic submission of certain data that the agency has deemed "necessary for CMS administration of the ESRD program," including information used to improve case-mix adjustment.[11] Dialysis facilities are required to furnish data and information for ESRD program administration, including (1) cost reports; (2) ESRD administrative forms; (3) patient survival information; and (4) existing ESRD clinical performance measures, and "any future clinical performance standards developed in accordance with a voluntary consensus standards process identified by the Secretary."[12]

Existing ESRD clinical performance measures do not include reporting of total dialysis treatment time.[13] Nor is total dialysis treatment time included in the other types of information contemplated in the relevant regulations as necessary for program administration. It is not data that is commonly included on a cost report or other administrative forms addressed in the regulation, nor is it data that providers currently capture. Finally, CMS has never made this reporting a condition of payment of otherwise clean claims.

In short, we believe that the Time Transmittal effectively creates new binding obligations on dialysis facilities beyond what is required by the terms of the applicable statutes and regulations. We seek a determination from HHS that the Time Transmittal is improper guidance, and request a prompt withdrawal of the Time Transmittal and related MLN article. Given that substantial investments must be made in order to prepare for the new reporting requirements starting April 1, 2021, we respectfully request that HHS act expeditiously to review the Time Transmittal in question and issue a decision on our petition.

Sincerely,

[redacted]

Kathleen A. Waters
Chief Legal Officer
DaVita Inc.

[11] *CMS, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities, 73 Fed. Reg. 20,370, 20,441 (April 15, 2008) ("The electronic data provided to CMS will be used . . . to help align our payment system with high-quality care through improvements in case-mix adjustment and the potential future use of payment for performance.").*

[12] *42 C.F.R. § 494.180(h).*

[13] *42 C.F.R. § 494.110(a)(2).*

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