June 25, 2018

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1694–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

BY ELECTRONIC DELIVERY

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2019 Rates Proposed Rule [CMS-1694-P]

Dear Administrator Verma:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the fiscal year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System (LTCH PPS) proposed rule.[1] ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 24,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include cancer program members, individual members, and members from 34 state oncology societies. It is estimated that 65 percent of cancer patients nationwide are treated by a member of ACCC.

ACCC appreciates the Centers for Medicare & Medicaid Services' (CMS) commitment to enhancing quality, improving patient access, and promoting value-driven innovation for Medicare beneficiaries. ACCC shares these values, which are central to our mission. We are eager to work with CMS to ensure that high quality cancer care continues to be accessible to all Medicare beneficiaries across the nation.

ACCC is deeply committed to promoting patient access to the most effective cancer treatments that are medically necessary given a patient's individualized needs. We further believe that it is vitally important to encourage ongoing innovation in the delivery of cancer care for all Americans. We are entering an exciting new era for cancer care with vast potential for breakthrough innovations that could reshape cancer treatment.

[1] 83 Fed. Reg. 20,164 (May 7, 2018).

New medical advances in immunotherapies such as chimeric antigen receptor T-cell (CAR T) therapy continue to expand the treatment toolkit of health care professionals. More technological developments are on the horizon. CAR Ts and other innovative new treatments carry transformative potential and may allow practitioners to reach significant populations of patients for which there might otherwise have been no effective treatment. We strongly believe that Medicare payment policy should recognize and encourage the adoption of these advances and thereby promote access to these medical innovations as soon as they are approved by the Food and Drug Administration (FDA).

ACCC believes that tremendous patient value is generated when innovative and effective cancer treatments are made accessible across all appropriate settings to patients who have a medical need for such care. Effective cancer treatment can save lives, and Medicare beneficiaries across the nation should have access to such care whenever medically necessary. We encourage CMS to adopt policies that ensure that the best available cancer treatments are accessible to all patients who need them. Toward that end, we offer the following comments and recommendations with respect to CMS's specific CAR T and other oncology related proposals.

I. Proposed CAR T Medicare Severity – Diagnosis Related Group (MS-DRG) Assignment[2]

CAR Ts and other immunotherapies are transforming the delivery of cancer care. These new and innovative treatments have life-saving potential and carry great clinical promise for small but significant patient populations that might otherwise lack viable treatment options.

ACCC strongly believes that CMS should ensure the availability of CAR Ts for all patients who need them and promote access to CAR Ts in all settings where it is safe and medically appropriate to provide them. We greatly appreciate CMS's thoughtful engagement on this important issue and the agency's willingness to include potential solutions in the proposed rule. ACCC acknowledges that there may be certain "unique challenges with respect to the MS–DRG assignment for procedures involving the utilization of CAR T-cell therapy drugs."[3] We appreciate CMS's openness to consider a range of alternative strategies to overcoming these challenges and are pleased to have the opportunity to work with the agency in exploring value and patient access driven solutions for CAR T reimbursement.

After careful evaluation of CMS's CAR T proposals, we believe that the best path forward is a solution that protects patient access in the short-term while opening a broader dialogue with regard to long-term solutions to the obstacles associated with Medicare payment for CAR Ts. A stepwise strategy to CAR T reimbursement would give CMS the benefit of flexibility in overcoming the obstacles associated with establishing an adequate MS-DRG classification (or other payment approach) for CAR Ts. It also would provide CMS with more time to collect cost data on a wider range of CAR T therapies before adopting a long-term payment strategy. This is important because CAR T technology is still in its early stages of development. Only the first two CAR Ts have thus far reached the market, and the technology is rapidly evolving. A long-term payment solution for all CAR T treatments could be premature. Given the changing landscape surrounding CAR Ts, additional time and data would be useful

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2 *Id.* at 20,188.

3 *Id.* at 20,189.

to ensure that any long-term approach is fully adequate to account for the growing range of different CAR Ts that are on the horizon for FDA approval in the near future.

For FY 2019, ACCC therefore believes that the most effective solution would be to adopt an MS-DRG assignment of 016 and a temporary pass-through on the invoice to account for the cost of the underlying acquisition costs of the biological. Our members tell us that an invoice-based payment approach for CAR Ts already is employed with success in the private sector; a number of commercial and Medicare Advantage (and several Medicaid) payers have adopted an invoice-based payment model in order to ensure adequate payment for CAR Ts during the initial stages of adoption of this innovative new technology. Implementing a similar interim pass-through for Medicare would give CMS the same benefit of added time to consider the most appropriate long-term payment solution without impeding patient access during the initial years of CAR T availability.

Further, CMS has experience in using pass-through payments to address exceptional situations implicating patient access (such as CAR Ts). CMS already uses a similar IPPS pass-through for blood clotting factors. Both the clotting factor and a CAR T pass-through would serve similar objectives: They both would be applied in unique situations where inadequacies of the default Medicare payment system cause barriers to the ability of a small but significant group of patients to access life-saving, medically necessary treatments.[4] Although CMS adopted the clotting factor pass-through pursuant to Congressional direction, nothing bars CMS from creating a similar pass-through for CAR Ts. CMS has authority to create such a pass-through under section 1886(d)(5)(I) of the Social Security Act (SSA) that "grants the Secretary broad discretion to make exceptions and adjustments" to payment under the IPPS "as []he 'deems appropriate.'"[5]

A pass-through also carries clear policy advantages for finalization in FY 2019. By setting Medicare reimbursement based on the invoice, or alternatively on average sales price[6] (ASP), providers would be assured consistent payment for CAR Ts that comes closer to approximating the providers' actual costs for furnishing these therapies. Payment under DRG 016 alone—even with the addition of new technology payments (NTAPs) and outliers—is not sufficient to support sustained access to CAR Ts. Providers cannot offset the current costs associated with CAR T therapies through administrative efficiencies. Reimbursement of CAR Ts should be set at a level where providers can feasibly provide these important therapies to the limited population of patients who need access to CAR Ts because no other treatments are available.

Further, the pass-through based approach would eliminate distortions in payment caused by charge compression. In other words, a pass-through would be a more effective way of operationalizing CMS's proposal to implement a cost-to-charge ratio (CCR) of 1.0. By basing the cost of the underlying biological directly on the acquisition cost itself (i.e., the invoice or ASP), CMS would eliminate any

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4 The clotting factor pass-through was adopted because inadequacies in the default payment rate (precipitated by dramatic increases in clotting factor prices) were dramatically hampering the ability of Medicare patients with hemophilia from having adequate access to blood clotting factors. *See generally* Explanation of Provisions Approved by S. Committee on Finance, 98th Cong. 2d Sess., S. Rpt. 98-169, vol. I, at 952 (Mar. 21, 1984).

5 *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 256 (D.D.C. 2015).

6 Unlike in the Hospital Outpatient Prospective Payment System (OPPS), we believe a temporary IPPS pass-through amount of ASP, updated quarterly, is appropriate, rather than ASP plus six percent, as hospitals would continue to be reimbursed through the underlying MS-DRG payment and also would be eligible for outlier payments.

distortion in the payment rates due to charge compression because CMS would be basing payment directly on acquisition cost.

Payment under a pass-through also would be more similar to reimbursement under the Medicare Hospital Outpatient Prospective Payment System (OPPS)—where a pass-through already exists that establishes payment based on a new drug or biological's average sale price (ASP) plus six percent. Increasing payment for CAR Ts administered in the inpatient setting to more closely approximate payment in the OPPS would help to ensure Medicare beneficiary access to care. ACCC believes that the best interest of the patient should drive the selection of setting of care. Accordingly, reimbursement for CAR Ts should be adequate in all settings—inpatient or outpatient, community-based or academic—where CAR Ts appropriately can be provided. CMS's payment policy should not be the driver of clinical decision-making about the best interest of patients. Nor should CMS's coverage policy impose undue additional burdens or restrictions on access to CAR Ts.[7] Rather, CAR Ts should be available and adequately reimbursed in all settings where it is safe and medically appropriate to provide them.

ACCC acknowledges that the adoption of an innovative pass-through could be challenging. We nonetheless believe that the novel challenges associated with CAR T reimbursement mandate equally creative solutions. We urge CMS to adopt a pass-through alternative as the most effective means available in the immediate-term to ensure patient access to this transformative new treatment.

If CMS declines to adopt a pass-through, we urge the agency to take other additional steps to make payment more adequate for CAR Ts. At a minimum, CMS should incorporate a CCR of 1.0 and grant new technology add-on payments (NTAP)[8] for the first two newly approved CAR Ts, Kymriah™ and Yescarta.™ These adjustments will be important mechanisms for improving the adequacy of CAR T reimbursement. Moreover, in the event a pass-through is not finalized, these two adjustments (as well as outlier payments) would become absolutely essential to reducing, though by no means eliminating, the dramatic financial losses that hospitals would face when providing CAR Ts and help preserve at least some patient access these innovative treatments.

Regardless of the proposal the agency finalizes in FY 2019, we also encourage CMS to begin an ongoing dialogue on CAR Ts. ACCC recognizes that the challenges associated with CAR T reimbursement could be difficult to resolve comprehensively in the current rulemaking cycle. In the longer-term, ACCC is open to exploring a MS-DRG specific to CAR T procedures in future rulemaking cycles. We believe that it would be challenging to establish an adequate CAR T MS-DRG for FY 2019,[9] but we recognize that a CAR T MS-DRG holds potential promise as a longer-term solution. We note, however, that any future CAR T MS-DRG option would only prove viable if CMS is open to proposing adjustments to correct for unique inequities that would otherwise arise under such a MS-DRG (e.g., an

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7 It would, for example, improperly restrict patient access to CAR Ts if CMS imposed unnecessary restrictions that impeded the ability of community-based providers to safely and appropriate offer CAR Ts.

8 We further encourage CMS to give due deference to the expert judgment of the FDA when evaluating the clinical efficacy of therapies. The FDA granted both Kymriah™ and Yescarta™ breakthrough therapy status in recognition of the substantial advantages these therapies offer over existing treatment options. ACCC does not believe that CMS should interpret the NTAP eligibility criteria in a manner that unnecessarily hampers the availability of NTAPs, which operate as important incentives for facilitating patient access to new and effective therapies for treating serious or life-threatening conditions.

9 Although CMS proposed a CAR T specific MS-DRG as one possible alternative, CMS did not provide information as to how payment rates would be calculated under the new MS-DRG, making it challenging to assess the adequacy of reimbursement under the proposal.

adjustment that prevents a CAR T MS-DRG from suffering dramatic, location-based differentials in payment due to how the wage index modifies the standard payment rate under the DRG payment formula). As we noted earlier, CMS has "broad discretion to make exceptions and adjustments" under section 1886(d)(5)(I) of the SSA to solve these challenges. Moreover, the collection of data on individual CAR Ts made possible through interim pass-through payment based on invoice or ASP data can help inform CMS's rate-setting process for any future CAR T MS-DRG. Collection of these data are essential, particularly given how new CAR T therapy is and how rapidly we expect the technology and patient treatment to evolve.

Going forward, ACCC is committed to collaborating with CMS toward a viable and adequate long-term payment solution for CAR Ts. We appreciates the agency's ongoing willingness to engage on these challenging questions of policy and urge CMS to take the maximum practicable steps in FY 2019 to preserve patient access to CAR Ts.

III. Proposed Changes to Regulations Governing Satellite Facilities[10]

ACCC believes that the hospital-within-a-hospital rules can often place a significant and often undue burden on IPPS-exempt hospitals—including the nation's eleven IPPS-exempt cancer hospitals. In certain situations, the hospital-within-a-hospital rules unnecessarily impede flexibility in regard to sharing of information and hospital governance, operations, and staffing structures. For example, the hospital-within-a-hospital rules incorporate outdated "separateness" requirements on staffing and governance that discourage IPPS-exempt hospitals from engaging in the type of integration of provider services that CMS has (in other situations) actively encouraged as benefiting patient-centered care. This narrow and inflexible view of separation discourages the efficient exchange of information and ignores the many potential clinical benefits of an IPPS-exempt hospital operating holistically within an integrated provider system. It is also inconsistent with CMS's own increasing recognition that greater health care integration is an important component of patient-driven care because it encourages more efficient delivery of services and often increases transparency for both physicians and patients.[11]

ACCC is pleased that, beginning on or after October 1, 2019, CMS has proposed to no longer preclude IPPS-exempt hospitals from having excluded psychiatric and/or rehabilitation units under the hospital-within-a-hospital rules. ACCC supports this initial step toward removing unnecessary burdens and restrictions on IPPS-exempt hospitals. As it moves forward in future rulemakings, we encourage CMS to consider other ways that CMS could modify its hospital-within-a-hospital rules' separateness requirements to reduce burdens on providers—including for IPPS-exempt hospitals that are co-located with IPPS hospitals. Among other things, we believe that CMS should re-consider whether the current hospital-within-a-hospital separateness criteria are too rigid and require unduly strict conditions of separateness even in situations where increased flexibility and integration would enhance patient well-being without raising significant potential for what CMS has described as inappropriate patient shifting.

10 83 Fed. Reg. at 20,450.

11 *Id.* at 20,550–53.

IV. Proposed Changes to PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)[12]

CMS proposes several updates to the PCHQR Program, including the adoption of three new factors for consideration in determining whether to retain a measure in the PCHQR Program,[13] adding one new measure for FY 2021, and removing up to six measures from the PCHQR Program.[14]

In general, we believe that it is important for the PCHQR Program to focus on measures that are meaningful for patients and hospitals. We share CMS's laudable objective of "mov[ing] the [PCHQR Program] forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in quality of care provided to patients."[15] Accordingly, as it continues to refine the PCHQR Program, we encourage CMS to be strategic in the measures its adopts for inclusion in the Program and, where appropriate, to eliminate those measures that unnecessarily increase burdens on hospitals and clinicians, while focusing on retaining those measures that generate the most informational value and which can be reported for a statistically significant number of patients.

ACCC also is pleased that CMS has proposed to begin considering hospital and clinician costs in assessing whether to retain existing PCHQR measures.[16] For hospitals and their staff, there are often significant costs associated with the collection of quality program measures data—both in terms of expenditure of provider resources and burdens on clinician time. ACCC believes that these costs and burdens are important factors that should be considered in deciding whether to retain a particular measure. Although CMS has proposed to apply its newly proposed cost factors on a case-by-case basis, ACCC believes that the costs and burdens on providers and clinicians should *always* be a significant consideration for the agency as it evaluates retention (or addition) of measures in the PCHQR Program. While ACCC believes that quality data is an important component of assessing (and thereby improving) quality, we also strongly believe that effective quality reporting is "parsimonious"[17] and focuses on only meaningful quality information that can be of material use in promoting discrete improvements in patient care.

With respect to the specific measures that CMS proposes for addition or removal, we encourage CMS to engage proactively with hospitals to identify and evaluate the most suitable quality measures for addition and/or retention in the PCHQR Program. ACCC believes there is significant value to such engagement. Hospitals (and their clinicians) are uniquely well-situated to evaluate the utility of a particular quality measure: They can evaluate both the practical clinical value associated with the data collected from a given measure, as well as provide real-world insights into the costs and burdens associated with the measure's collection. Such insights should be given due weight by CMS and inform the agency's ultimate decision with respect to whether a particular measure is appropriate for inclusion or retention in the PCHQR Program.

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12 *Id.* at 20,500.

13 *Id.* at 20,501.

14 *Id.* at 20,502–03 (for two of the six measures proposed for removal, CMS proposes the removal only if the agency finalizes its proposal to begin considering certain new factors when deciding whether to retain a measure).

15 *Id.* at 20,502.

16 *See id.* at 20,501.

17 *Id.* at 20,502.

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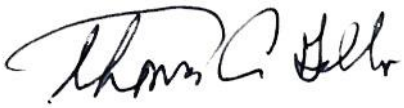
ACCC greatly appreciates the opportunity to comment on the FY 2019 IPPS proposed rule. ACCC reiterates its commitment to promoting access to effective cancer treatments for all Medicare beneficiaries who need them—including by encouraging access to innovative and effective new treatments such as CAR Ts in all settings and situations where such treatments are medically appropriate and suitable given a particular patient's needs.

If you have any questions about our comment letter or would like to discuss our comment in further detail, please contact Leah Ralph, ACCC Director of Health Policy, at lralph@accc-cancer.org or (301) 984-9496, ext. 223.

Respectfully submitted,



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