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IDSA
Infectious Diseases Society of America

December 28, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-1869-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, Maryland 21244-8013

Submitted electronically via http://www.regulations.gov

Re: Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations

Dear Administrator Verma,

The Infectious Diseases Society of America (IDSA) appreciates the opportunity to provide comments on the Final Rule for the 2019 Home Health Prospective Payment System. IDSA represents more than 11,000 infectious diseases (ID) physicians, scientists, and other healthcare professionals devoted to patient care, prevention, public health, education, and research in infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, health care-associated infections, antibiotic resistant bacterial infections, as well as infectious disease outbreaks and emerging infections such as the Middle East Respiratory Syndrome coronavirus (MERS-CoV), Ebola virus and Zika virus. prolonged

IDSA members are committed to improving the quality and the safety of patient care in all healthcare settings and health systems across the nation. Our members lead to the ground efforts to combat healthcare associated infections and antimicrobial resistance. The specialty of infectious diseases is unique in that it is the only specialty who's training routinely emphasizes the linkage between individual patient care and how this care leads to impacts on the larger patient population. It is with this background that we provide comment on the final rule related to transitional payment for home infusion therapy services.

Outpatient Parenteral Antimicrobial Therapy (OPAT)

OPAT, defined as the administration of parenteral antimicrobial therapy in at least two doses on different days without intervening hospitalization[1], has long been the standard of care to treat an infection that requires prolonged IV antimicrobials outside the acute care setting. OPAT is less expensive than hospital-based treatment and compared to alternatives such as skilled nursing facility administration of medications, this method is preferred by most patients.[2] In fact, according to a 2006 Emerging Infections Network (EIN) survey of ID physicians in North America, 89% of respondents reported their patients received OPAT in the home.[3] This high number is due to most insurers, including many state Medicaid programs, most Medicare Advantage plans, the Veterans Administration, private insurers, Tricare, and the Federal Employee Health Plan, covering the costs OPAT.[4] Furthermore, the recently published results of a commercial claims analysis that compared ID physician-led OPAT to OPAT without ID physician involvement showed that ID consultations during OPAT are associated with large and significant reductions in the rates of emergency department (ED) admission and hospital admission in the 30 days after index events, as well as lower total healthcare spending.[5]

A study commissioned by the National Home Infusion Association (NHIA) assessed the potential Medicare savings of expanding Medicare coverage of infusion therapy in the home, and estimated a savings of $80 million, approximately 12.6% of the overall cost of infusion services that migrate from hospital outpatient departments (HOPDs), physician offices, and skilled nursing facilities (SNFs) to home for the 10-year period from 2015 to 2024.[6] Congress recognized the value of home infusion therapy services to Medicare and its beneficiaries, which is why the benefit was established under the 21st Century Cures Act and why it established a temporary transitional payment under the Bipartisan Budget Act of 2018.

IDSA appreciates the Agency's efforts to develop a payment model to support home infusion. Most ID physicians in clinical practice use OPAT as many patients who are discharged from the hospital to complete their antimicrobial course of therapy, rather than remain as an inpatient or be transferred to a post-acute care (PAC) facility. ID physicians actively oversee these care transitions providing monitoring and longitudinal support to ensure patients are effectively and safely treated. This ID oversight is particularly important as there is a complex and sometimes fragmented healthcare delivery process that involves pharmacy operations, durable medical equipment (DME) supplies, home health nursing (as needed), safety-based laboratory testing, and other physician services.

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[1] https://academic.oup.com/cid/article/68/1/e1/5175018

[2] https://www.idsociety.org/news--publications-new/articles/2018/id-specialist-input-improves-outcomes-for--outpatient-parenteral-antimicrobial-therapy-new-idsa-guidelines/

[3] https://academic.oup.com/cid/article/43/10/1290/515800

[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4657539/

[5] Shah A, Petrak R, Fliegelman R, Shrestha N, Allison G, Zurlo J, Parker S, Poretz D, McKinsey D, Dougherty M, Martinelli L, Mathur A, Rodriguez A, Smith MW. Infectious Diseases Specialty Intervention Is Associated with Better Outcomes Among Privately Insured Individuals Receiving Outpatient Parenteral Antimicrobial Therapy, Clinical Infectious Diseases, ciy674, https://doi.org/10.1093/cid/ciy674

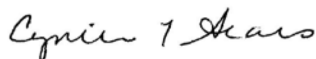
[6] http://www.nhia.org/resource/legislative/documents/AvalereFinalHomeInfusionReport.pdf

We have concerns about how the payment model is expected to function based on the Agency's interpretation of the "*infusion drug administration calendar day"* and the associated reimbursement for the services and supplies. CMS has defined *infusion drug administration calendar day* for the home infusion therapy services temporary transitional payment to mean "payment is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel."[7]

We note that the 21st Centuries Cures Act called for the single payment to a home infusion therapy supplier to consider, as appropriate, the types of infusion therapy, including variations in utilization of services by therapy type. As defined, the home infusion therapy benefit would face serious implementation challenges for Medicare beneficiaries who require OPAT. One consideration is that the requirement for a skilled professional to be present for the infusion does not reflect the standard of care for most OPAT cases. Except for extraordinary circumstances, the clear majority OPAT recipients can be adequately trained to perform the OPAT infusion without requiring a skilled professional to be present for most of their treatment course. Moreover, in OPAT cases where multiple infusions per day are required depending on pharmacokinetics of the antimicrobial selected, the physician may opt to use a more expensive drug with once-a-day dosing to fit this payment model, rather than having a skilled professional make multiple visits in the same day. For these cases, we are concerned that cost-savings potential for OPAT may not be realized. Finally, IDSA is concerned that the proposed definition of and payment amount for the *infusion drug administration calendar day* fails to fully account for the cost of the services provided or the underlying operational resources needed to support the provision of such services, such as the costs associated with ensuring 24/7 support.

We urge CMS to work with IDSA and other stakeholders on a more accurate interpretation of *infusion drug administration calendar day* that reflects the diverse array of services required to furnish infusion services in the patient's home safely. If you have any questions, please contact Andrés Rodríguez, Vice President, Clinical Affairs and Practice Guidelines at 703-299-5146 or arodriguez@idsociety.org.

Sincerely,



Cynthia L. Sears, MD, FIDSA
President

[7] 42 CFR Parts 409, 424, 484, 486, and 488.