

August 24, 2020

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Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1730-P
P.O. Box 8013
Baltimore, MD 21244-8013

Submitted Electronically at www.regulations.gov

Re: Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements

Dear Administrator Verma,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the *Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements (CMS-1730-P)* proposed rule with comment period published in the Federal Register on June 30, 2020.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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Telehealth

In the first COVID-19 public health emergency (PHE) interim final rule with comment period (IFC) the Centers for Medicare and Medicaid Services (CMS), on an interim basis, permitted the use of telecommunications technology as part of the home health plan of care as long as it did not replace in-person visits under the existing home health plan of care. The frequency of and reason for in-person home health visits and visits performed through telecommunications technology are outlined in the patient's plan of care – a remote visit may not replace one of these in-person visits, and appropriately skilled staff must administer the service. CMS believed that this flexibility would increase access to technologies, such as telemedicine and remote patient monitoring, during the PHE.

In the 2021 Home Health proposed rule, CMS is proposing to make this flexibility permanent beginning January 1, 2021. This would mean that home health agencies (HHAs) can continue to utilize telecommunications technologies in providing care to beneficiaries under the Medicare home health benefit beyond the COVID-19 PHE, as long as the telecommunications technology is related to the skilled services being furnished, is outlined on the plan of care, and is tied to a specific goal indicating how such use would facilitate treatment outcomes.

ASCO supports CMS' proposal to permit patient services and/or monitoring performed through telecommunication technology on a permanent basis when such services are included as part of the home health plan of care.

ASCO supports CMS' proposal to make this temporary flexibility provided during the COVID-19 PHE a permanent part of the Medicare home health program. This proposal will ensure patient access to the latest technology and give home health agencies the confidence that they can continue to use telecommunications technology as part of patient care beyond the PHE. Cancer patients, because they are often immuno-compromised, are an especially vulnerable subset of the Medicare population. Granting HHAs the flexibility to provide clinically appropriate and high-quality care to these beneficiaries through technology can help keep these vulnerable patients in their homes, reducing unnecessary exposure to all illnesses, not just COVID-19.

Home Infusion Benefit

Section 5012 of the 21st Century Cures Act (the Cures Act) established a new and separate Medicare home infusion therapy services benefit to be fully implemented on January 1, 2021. As required by section 1861(iii)(2) of the Social Security Act (the Act), home infusion therapy covers the professional services furnished in accordance with the plan of care, patient training and education not otherwise covered under the durable medical equipment benefit, remote monitoring, and monitoring services for the provision of home infusion for the safe and effective administration of certain drugs and biologicals. The Act also requires the Secretary to implement a payment system beginning January 1, 2021 under which a single payment is made to a qualified home infusion therapy supplier for the services previously described. This statutory provision limits the single payment amount so that it cannot reflect more than 5 hours of infusion for a particular therapy per calendar day. In this 2021 Home Health proposed rule CMS establishes payment rates for the three categories of home health infusions (including chemotherapy), excludes the home infusion benefit from the home health benefit, and sets enrollment standards for qualified home infusion therapy suppliers.

ASCO has significant concerns about the safety of home infusion for chemotherapy drugs and does not support its use, unless there are extraordinary circumstances and a treating physician—in consultation with the patient—has determined it is the most appropriate alternative.

The safety of patients is of utmost importance for oncologists and health care teams providing cancer care. Anticancer drugs, particularly infusions of cytotoxic chemotherapy, can be extremely dangerous if administered incorrectly, spilled, or mishandled. Antineoplastic drugs are effective at treating cancer but can be extremely toxic to normal human cells. A well-characterized list of negative health effects includes genotoxicity, teratogenicity, acute allergic reactions, carcinogenicity, and reproductive risks

among others, potentially affecting both patients and health care personnel.^{1,2} These safety concerns are what prompted ASCO to develop chemotherapy administration safety standards with the Oncology Nursing Society; however, these standards are specific to the outpatient setting and do not address specific safety concerns that could arise from home chemotherapy infusion.^{3,4} Furthermore, many of these safety standards may be difficult to satisfy in the home infusion setting. ASCO is concerned that routine use of home infusions for anticancer therapy could potentially fail to provide the safeguards to both patients and health care providers called for in existing safety standards thereby exposing patient and provider to unnecessary risk.

While ASCO generally does not support home infusion of anticancer therapy services when the benefits do not outweigh the potential risks, we do recognize that the home infusion benefit is statutorily required and that the current list of chemotherapies approved for home infusion are already on the Medicare durable medical equipment list of approved drugs. Additionally, we appreciate that the intention of this benefit is to increase Medicare beneficiary access to services.

Removing obstacles to routine cancer treatment through home infusion may represent a promising option (for example, in rural populations and to decrease infection exposure), but there is insufficient evidence demonstrating feasibility and safety. ASCO provides policy recommendations⁵ based on evidence; without sufficient research directly comparing the safety of chemotherapy infusions in the home and outpatient settings, we do not support home infusion of chemotherapy without significant caveats. Most published literature examines home infusion in general, which is of limited utility in the oncology setting given the toxicity and hazardous materials specific to chemotherapy.

It is important to acknowledge that the safety concerns posed are not uniform across anticancer therapies, varying by drug or by class of drug. Establishing safe home infusion will require programs to be flexible and rely upon oncology experts to determine the optimal and safest plan for any individual patient.

Given ASCO's safety concerns, the lack of evidence, and the expertise of oncology physicians we ask that:

- **CMS consult closely with oncology experts prior to the 2021 implementation of the Home Infusion benefit to ensure that home infusion of chemotherapy is only used when determined by the treating physician and patient to be the most appropriate setting for certain classes of drugs.**

¹ Hoffman, D. M. "Reproductive risks associated with exposure to antineoplastic agents: a review of the literature." *Hospital pharmacy* 21.10 (1986): 930-2.

² Valanis, Barbara G., et al. "Association of antineoplastic drug handling with acute adverse effects in pharmacy personnel." *American Journal of Hospital Pharmacy* 50.3 (1993): 455-462.

³ Jacobson JO, Polovich M, Gilmore TR, et al: Revisions to the 2009 American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards: Expanding the scope to include inpatient settings. *J Oncol Pract* 8:2-6, 2012.

⁴ Neuss, Michael N., et al. 2016 updated American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards, including standards for pediatric oncology. *J Oncol Pract* 12.12 (2016): 1262-1271.

⁵ Home Infusion Position Statement Available at: https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2020_Home-Infusion-Position-Statement.pdf?cid=DM5714&bid=53107332

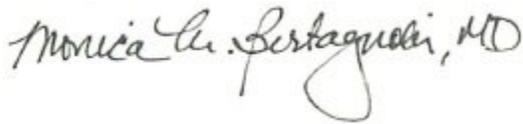
- **CMS require quality reporting for home infusion therapy services through the collection of oncology-specific measures to enable evaluation of safety related to anticancer therapy administration.**
- **CMS work closely with oncology experts before making additional chemotherapies available through the home infusion benefit should this be a consideration in future years.**
- **CMS require verification that necessary safety protocols and precautions are in place when administering anticancer therapies in the home to protect health care personnel, patients and caregivers.**

We encourage CMS to also refer to ASCO's newly-released Home Infusion of [Anticancer Therapy Position Statement](#) for additional details on our position regarding home infusion of chemotherapy.

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We appreciate the opportunity to comment on the *2021 Home Health* proposed rule. Please contact Gina Baxter (gina.baxter@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,

A handwritten signature in cursive script that reads "Monica Bertagnolli, MD". The signature is written in black ink and is positioned below the word "Sincerely,".

Monica Bertagnolli, MD, FACS, FASCO

Chair of the Board

Association for Clinical Oncology