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May 4, 2020

**VIA ELECTRONIC FILING** – <http://www.regulations.gov/>

Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
P.O. Box 8016  
Baltimore, MD 21244-8016

**Re: CMS-1744-IFC; Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency**

Dear Administrator Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments to the Center for Medicare & Medicaid Services (CMS) on the Interim Final Rule with Comment Period (IFC) Response to the COVID-19 Public Health Emergency. PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$900 billion in the search for new treatments and cures, including an estimated \$79.6 billion in 2018 alone.

As reflected in the March 30 IFC and many other important policy actions taken by CMS, our nation faces an unprecedented challenge in combatting COVID-19. America's biopharmaceutical research companies are doing all they can to rise to this challenge. Our sector will continue to work with health care partners across the world to do everything possible to beat this virus as quickly and as safely as possible. Already, our members have significant efforts underway researching and developing new potential vaccines and treatments and testing existing medicines.

As you know, U.S. patients and providers are facing unprecedented disruptions in care delivery as a result of the COVID-19 public health emergency (PHE). Emerging news reports and data are showing that these disruptions pose significant risks to patients who rely on office-based care – such as beneficiaries receiving infused or injected medicines under Medicare Part B. Patients are currently facing the very serious dilemma of risking exposure to COVID-19 infection or delaying treatment for serious diseases and conditions like cancer, multiple sclerosis, and immune disorders.<sup>1</sup>

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<sup>1</sup> See e.g., Sheth S. CNN. "Cancer patients like me face a dystopian nightmare amid the virus." April 16, 2020. <https://www.cnn.com/2020/04/16/opinions/cancer-during-covid-19-pandemic-sheth/index.html>

Medical practices across the country are seeing widespread impact due to COVID-19. A recent survey showed that across practice areas, outpatient visits are down between 40 and 60 percent, with autoimmune specialties reporting the greatest impact.<sup>2</sup> In addition, one quarter of nephrologists (kidney specialists) in the survey said they are more likely to start patients on a home modality of dialysis versus a regimen requiring an office visit.<sup>3</sup> Large hospital systems like the University of Pennsylvania (Penn) are increasingly turning to providing cancer care in the home to avoid having patients with compromised immune systems come into the hospital for treatment.<sup>4</sup> Patients who rely on osteoporosis shots to defend against risk of fractures are missing doses because of offices closures due to COVID-19.<sup>5</sup> Further, a variety of therapies require ongoing monitoring that requires analysis of whole blood, or other clinical laboratory services. The PHE is also creating obstacles to patients accessing routine laboratory monitoring services that could disrupt their safe access to prescribed medications.

These care disruptions fall heavily on Medicare beneficiaries, particularly those with comorbidities, who are a high-risk group for experiencing higher rates of serious complications and mortality due to COVID-19. During this PHE, it is critically important to give patients and their physicians as broad a range of tools as possible to ensure that Medicare beneficiaries have continued access to treatments in ways that do not expose them to infection in providers' offices or hospital outpatient departments. While we recognize that this may necessitate varying modes of care delivery and certain flexibilities granted during the emergency period to better meet patient safety needs (e.g. telehealth), we stress the importance that these flexibilities should not depart from statutory requirements or other standards that are integrally important and fundamental to the integrity of federal programs that may be affected.

We appreciate the important initial steps CMS took in the IFC in recognizing that during the current crisis there will be situations where a patient cannot access in-office care and needs to receive a Part B medicine in the home,<sup>6</sup> however, we are concerned that some of the implementation barriers to CMS's policy changes could leave patients without appropriate access to services that CMS intended they be able to receive.

Our comments address the following concerns and provide alternative solutions for CMS to consider:

- While the IFC recognizes that patients now confined to their home may need to receive Part B medicines in their home, it is limited in that it relies on physician supervision via telemedicine. The IFC's telemedicine-based flexibility will be very difficult if not impossible for many practices (particularly smaller practices with fewer resources) to implement in a timely way due to the particular administrative and financial burdens it creates. We are concerned that many physician practices will not be able to overcome the operational and financial barriers to implement the IFC's telemedicine-based model. Additionally, we recognize that there may be potential limitations for patients to interface with telemedicine platforms at the point of care, including challenges in coordinating sessions. We urge CMS to modify the IFC to cover Part B

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<sup>2</sup> Piper Sandler. "Multi-Specialty Doc Survey Points to Massive Near-Term CoV019 Disruptions." March 26, 2020.

<sup>3</sup> Id.

<sup>4</sup> McCullough M. Philadelphia Inquirer. "Coronavirus Threat Spurs Movement of Cancer Care Into Homes." April 15, 2020. <https://www.inquirer.com/health/coronavirus/coronavirus-shifts-cancer-treatment-from-hospitals-to-homes-20200415.html>

<sup>5</sup> Dr. John P. Bilezikian, Professor of Medicine, Vagelos College of Physicians and Surgeons, Columbia University. April 3, 2020.

<sup>6</sup> Center for Medicare & Medicaid Services, Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 19245 (April 6, 2020) <https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf>

treatments when physicians refer patients to a broader range of providers to meet their patients' needs during the current public health emergency.

- The Department of Health and Human Services (HHS) should use its emergency authority under Section 1135 of the Social Security Act (SSA) to quickly modify the IFC to permit home health agencies (HHA), home infusion companies, and similar qualified entities to buy, bill and administer Part B drugs when the patient's physician determines it is appropriate to do so. This additional flexibility can be implemented under the authority granted by Sec. 1135 and would permit physicians to refer patients to qualified entities when the provider deems it is safe and appropriate for those entities to administer Part B medicines in the home.
- CMS should clarify the expanded coverage of drugs administered through durable medical equipment (DME) during the PHE to ensure it will cover drugs and biologicals that can be safely administered through DME for all reasonable and necessary indications.
- CMS should include flexibilities for blood draws and other specimen collection by qualified health care professionals to be conducted in patients' homes during the PHE to ensure that Medicare beneficiaries maintain safe access to therapies.
- CMS should consider using emergency funds and increasing the payment for the administration of all Part B medicines during the COVID-19 PHE.

**I. THE FLEXIBILITIES PROVIDED UNDER THE CURRENT IFC, WHILE IMPORTANT, WILL BE DIFFICULT OR IMPOSSIBLE FOR SOME PRACTICES TO IMPLEMENT FOR HOME ADMINISTRATION OF PART B MEDICINES.**

During the COVID-19 public health emergency (PHE), CMS has taken crucial steps to help Medicare beneficiaries obtain necessary items and services safely at home, without being exposed to the novel coronavirus at hospital outpatient facilities or physicians' offices. In order to ensure continued beneficiary access to Part B drugs, any policy reforms undertaken during the public health emergency must address the specific "incident-to" rules for Part B medicines.

Medicare Part B covers drugs that are "not usually self-administered" when they are furnished "incident to" physicians' professional services.<sup>7</sup> Current CMS guidance provides that to meet the incident-to coverage requirements, a "not usually self-administered" drug must meet the following criteria:

Must be furnished by a physician; and

Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision [also called 'direct' supervision].

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<sup>7</sup> Social Security Act (SSA) § 1861(s)(2)(A).

The charge ...for the drug or biological must be included in the physician’s bill, and the cost of the drug or biological must represent an expense to the physician.<sup>8</sup>

CMS generally interprets the “direct supervision” requirement to mean that the physician need not be in the room where the procedure is being performed, but must be “present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure.”<sup>9</sup> CMS began adapting this requirement to the COVID-19 crisis in the interim final rule with comment (IFC),<sup>10</sup> by revising the direct supervision definition to include supervision via real-time interactive audio and video technology during the PHE.<sup>11</sup> Further, CMS clarified in an April 7, 2020 “Office Hours” call that direct supervision – ordinary or virtual – requires that physicians be “immediately available” to furnish assistance and direction, but not that they must be in the room/participating via telecommunication technology throughout the procedure.<sup>12</sup> To ensure that physicians know of this clarification, CMS should incorporate this guidance into the text or preamble of its final rule.

These changes to the “direct supervision” definition are important and we commend CMS for adopting them. However, these changes do not provide sufficient flexibility to meet many Medicare patients’ needs, in part because the remaining “incident to” criteria have not been modified. Without additional modifications to these criteria, physicians could only use their employees or contractors (or leased personnel of contractors) to administer patients’ prescribed drugs in their homes; and they would have to buy the drugs administered to their patients and bill Medicare for the drugs and administration services. To administer the drugs through a contractor, the physician would also have to contract with that entity and pay the entity for the drugs and administration services (instead of the contractor just billing Medicare directly for the drugs and services). We are concerned that this set of requirements is complicating home administration of drugs and thus reducing its use – resulting in beneficiaries either unnecessarily going to healthcare facilities to get their drugs administered and risking infection, or foregoing treatment.

Many providers do not have the portable equipment necessary to serve patients in their home using their own staff. In order to operationalize this, providers who are already facing reduced revenue would have to purchase medical items like portable infusion pumps, portable IV bag hangers, personal protective equipment (PPE), and equipment to move supplies in a sterile environment. We are concerned that not only is this an additional financial burden on providers, but even those that may have excess capital, still might not be able to purchase items when so many current customers are

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<sup>8</sup> Medicare Benefit Policy Manual ch. 15 sec. 50.3. See also 42 C.F.R § 410.26 (incident-to regulation).

<sup>9</sup> 42 C.F.R. § 410.32(b)(3)(ii).

<sup>10</sup> CMS, Medicare and Medicaid Programs: Interim Final Rule on Medicare and Medicaid Policy and Technical Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed.Reg. 19230 (April 6, 2020).

<sup>11</sup> 85 Fed. Reg. at 19245, 19286 (revised 42 C.F.R. 410.32(b)(3)(ii)). In the hospital outpatient setting, administration of Part B drugs requires “general supervision.”

<sup>12</sup> Transcript of April 7, 202 CMS Office Hours call with hospitals and health systems at 20:

Caller: .... to meet the direct supervision requirement, so that he or she is immediately available should there be a need, do they [physicians] need to be on a consistent open line via telehealth, or is it sufficient if the physician might be available – you know, in an instant, right, that they know that they’re supervising infusion. Can you comment on which is acceptable?

CMS Staff: ... I think the use of virtual presence was intended to replace the need for the in-person presence, and so, to the extent that the in-person presence wasn’t personal supervision, so it wasn’t necessarily in the room during the entire course of the service, but rather, immediately available in person, the same thing would be true of the virtual presence.

experiencing shortages of medical supplies and equipment.<sup>13</sup> Most independent physician practices do not have existing contracts or relationships with companies that supply this equipment. We are concerned that new purchasers will be de-prioritized after existing customers, creating an additional operational barrier. Finally, most independent physician practices do not have enough staff, or staff that is adequately trained to provide infusions or injections in the home, and additional training would be needed for small practices and individual providers to be able to send nurses into homes.

Another option for providers under the current IFC is to contract with entities that have the staff and supplies necessary to facilitate home administration for patients. However, these relationships do not always exist, and providers would have to enter into new contracts. This adds an additional layer of complexity in order to operationalize home administration of Part B medicines. Because the IFC requires physicians to still “buy and bill” for Part B medicines, they would have to enter into new contracts, including having to negotiate fees, creating an additional financial burden on already struggling physician practices.

For these reasons, additional flexibilities are still needed to allow additional entities, like home infusion companies and home health agencies, to serve Part B fee-for-service (FFS) patients in the home when deemed safe and appropriate by physicians.

## **II. HHS SHOULD USE ITS EMERGENCY AUTHORITY UNDER SECTION 1135 TO ALLOW ADDITIONAL ENTITIES TO ADMINISTER PART B MEDICINES IN THE HOME.**

To give physicians and patients the added flexibility they need during the PHE, CMS should use the emergency authority in Social Security Act (SSA) § 1135, “Authority to Waive requirements During National Emergencies” to facilitate broader access to Part B medicines in the home. This statute authorizes CMS to “waive or modify the application of” several Medicare, Medicaid or CHIP provisions in an emergency. Specifically, SSA § 1135 authorizes CMS, for purposes of ensuring that healthcare items and services are sufficiently available to meet beneficiary needs and providers acting in good faith are not denied reimbursement for noncompliance, “to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area ... during any .... emergency period, the requirements of [the Medicare, Medicaid, and CHIP statutes] or any regulation thereunder ... pertaining to—

- (A) conditions of participation or other certification requirements for an individual health care provider or types of providers,
- (B) program participation and similar requirements for an individual health care provider or types of providers, and
- (C) pre-approval requirements;<sup>14</sup>

Importantly, this statute allows CMS to pay for non-self-administrable drugs and related administration services performed in the home by modifying some of the incident-to regulations during the PHE, as these regulatory requirements are “similar to” program participation requirements for physicians.

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<sup>13</sup> Ranney M, Griffith V, Jha A. The New England Journal of Medicine. “Critical Supply Shortages – The Need for Ventilators and Personal Protective Equipment during the COVID-19 Pandemic.” March 25, 2020. <https://www.nejm.org/doi/full/10.1056/NEJMp2006141>

<sup>14</sup> SSA § 1135(b)(1)(emphasis added).

Without the ability to waive or modify requirements similar to program participation requirements, part of § 1135 would become superfluous – and a key canon of statutory interpretation requires that statutes be construed “so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.”<sup>15</sup>

Thus, § 1135 affords CMS well-grounded authority during the PHE to ensure that beneficiaries who stay at home to reduce contagion risks or for other public health reasons can access necessary non-self-administrable drugs through a range of qualified providers that may administer the drugs in beneficiaries’ homes and receive Medicare payment without fully satisfying the incident-to regulations. Specifically, CMS could modify the application of the incident-to regulations – which are “similar to” physicians’ program participation requirements – by permitting healthcare entities that commonly administer drugs in patients’ homes (e.g., home health agencies or home infusion therapy suppliers<sup>16</sup>) to carry out the incident-to functions for Part B drugs (purchasing the drugs, administering the drugs, and billing the drugs and administration services to Medicare) once the physician prescribed a drug and requested that the entity administer it to the patient at home.<sup>17</sup> The physician would continue to direct the patient’s treatment as usual and the home drug administration would be an integral part of his or her treatment of the patient. The main difference from the ordinary incident-to requirements (as revised in the IFC) would be that the physician would not be required to perform tasks such as buying and billing the drugs and contracting with the entity that stands in their shoes and administers the drugs in the home, and therefore could more easily offer patients home administration of their Part B drugs during the PHE.

The simplified incident-to arrangements outlined above would further the purposes of SSA § 1135 – giving CMS “the ability to pay providers for services rendered in good faith during an emergency, even if certain paperwork or other regulations are not followed”<sup>18</sup> -- and comply with the incident-to requirement in the Medicare statute. The Medicare statute does not require (1) that drugs covered by Part B incident to physicians’ professional services are always administered by the physician or a person or entity employed by or under contract with the physician, or (2) that the physician always purchase the drugs and bill Medicare for them. Instead, the key requirement is that incident-to items be “of kinds which are commonly furnished in physicians’ offices and are commonly either rendered without charge or included in the physicians’ bills.”<sup>19</sup> Non-self-administered drugs that “commonly” are furnished in

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<sup>15</sup> Corley v. United States, 556 U.S. 303, 314 (2009)(quoting Hibbs v. Winn, 542 U.S. 88, 101 (2004)). See also, e.g., Colautti v. Franklin, 439 U.S. 379, 392 (1979) (“Appellants’ argument . . . would make either the first or the second condition redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative.”); Yates v. United States, 135 S. Ct. 1074, 1085 (2015) (plurality opinion) (rejecting an interpretation that would “render superfluous an entire provision passed in proximity as part of the same Act”); Bailey v. United States, 516 U.S. 137, 146 (1995) (“We assume that Congress used two terms because it intended each term to have a particular, non-superfluous meaning.”).

<sup>16</sup> CMS could specify the types of qualified non-physician suppliers or providers that could administer non-self-administrable drugs to beneficiaries in their homes, and in fact already has issued an FAQ (“how can beneficiaries who are not leaving their home get infusion therapy?”) citing entities that can provide home administration of drugs under existing Medicare policy. CMS, COVID-19 Interim Final Rule FAQs (updated April 9, 2020) at 22.

<sup>17</sup> We do not mean that home health agencies would be providing home health benefits (the home health benefit excludes drugs other than certain osteoporosis drugs), but rather that home health agencies or other types of entities qualified to dispense drugs and administer drugs in patients’ homes) could stand in the shoes of the physician for purposes of the “incident to physicians’ professional services” benefit under SSA § 1861(s)(2)(A).

<sup>18</sup> May 23, 2002 Congressional Record S4780 (remarks of Sen. Baucus).

<sup>19</sup> See SSA § 1861(s)(2)(A) (“medical and other health services” covered by Part B include “services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician’s professional

physician offices and included in physician bills may be furnished under different arrangements in an emergency and still meet the letter and purpose of the statutory requirements.

**A. During the time of the COVID-19 PHE, treating providers need temporary and voluntary flexibility to refer patients to additional entities to treat the broadest number of patients.**

Prescribing physicians need every option available to them during this PHE, including the ability to refer patients to entities that are currently providing administration of traditional Part B medicines in the home for patients with commercial or Medicare Advantage (MA) coverage. We recognize that home administration will not be the best option for all patients, or all medicines. In some cases, the services patients need to ensure their safety may only be available in a physician office or infusion center. At the same time, as recognized by CMS in its IFC, the COVID-19 health emergency creates a new set of risks and challenges, and in this environment, providers need every tool available to them to treat as many patients as possible. Rather than trying to parse out at a policy level which patients should and should not have access to home infusion, we believe the best approach is a policy that provides broad flexibility and leaves care setting decisions about individual patients firmly in the hands of the treating physician. We are encouraged by the IFC released on April 30<sup>th</sup>, 2020, that gave additional flexibility to hospitals to treat the patient's home as a hospital location in certain circumstances.<sup>20</sup> In the April 30<sup>th</sup> IFC, CMS recognized that providers may need the flexibility to provide drugs and drug administration services in patients' homes and granted hospitals the ability to treat beneficiaries' homes as hospital outpatient departments for purposes of furnishing and billing for services in the home. We believe that independent physicians should be given greater flexibility to work with additional entities to serve their patients in the home. In taking this approach, the commercial market provides a useful reference.

The private insurance market allows for home administration for many of the medicines that would temporarily be available under this new flexibility. Many commercial and MA plans have already shifted to home administration for medicines traditionally administered in a physician office or hospital outpatient department.<sup>21</sup> Under this system, the treating physician writes the prescription for the medicine and then refers patients to home infusion companies or home health agencies that already have the specific training and equipment necessary to infuse or inject medicines in the home immediately.<sup>22</sup> That company then works with patients to determine the best way to provide for administration in the home.<sup>23</sup> These companies purchase and bill for the drug and its administration. However, Medicare FFS has more restrictive guidance on home administration than these other payers.<sup>24</sup>

Currently, immunocompromised patients or those with open wounds often receive administration at home to reduce their exposure to additional pathogens. Patients with diagnoses like infections, some types of colon cancer, arthritis, septicemia, pneumonia, and fluid/electrolyte deficiencies are among the

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service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills (or would have been so included but for the application of section 1847B [the Competitive Acquisition Program])(emphasis added).

<sup>20</sup> Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program. RIN 0938-AU32. April 30, 2020. <https://www.cms.gov/files/document/covid-medicare-and-medicare-ifc2.pdf>

<sup>21</sup> Xcenda Market Research, 2017

<sup>22</sup> Xcenda Market Research, 2017

<sup>23</sup> Xcenda Market Research, 2017

<sup>24</sup> Xcenda Market Research, 2017

populations already receiving infusions or injections at home.<sup>25</sup> The decision to allow for home administration remains up to the physician, but antibiotics to treat infections, hydration and nutrition medications, pain management, and immunoglobulin are currently administered to appropriate patients in the home.<sup>26</sup> The National Comprehensive Cancer Network (NCCN) re-issued a 2018 report on site of care for oncology treatments, acknowledging that in-home delivery for some cancer therapies is possible.<sup>27</sup> The NCCN recommendations, while not comprehensive and do not evaluate newer therapies, identify some chemotherapies and antineoplastic agents where home administration is possible.

In addition, major centers like the University of Pennsylvania have already recognized that there are some instances where home administration is safe and appropriate and had begun pilot programs to test home delivery prior to the COVID-19 PHE.<sup>28</sup> Penn Medicine recently expanded the home infusion pilot program to accommodate more patients during the COVID-19 PHE, delivered by qualified nurses and other practitioners. Penn Home Infusion Therapy already provided parenteral and enteral nutrition, intravenous gamma globulin,<sup>29</sup> colony stimulating factors, inotropic therapy, chemotherapy, pain management medicines, IV fluids, and antibiotics to patients in the home.<sup>30</sup> Penn Medicine is expected to continue to expand this program to serve as many patients as possible.<sup>31</sup>

To provide as much support as possible for physicians during the PHE, CMS should allow for physicians, when they deem it is safe and appropriate, to refer patients to additional qualified entities: nurse practitioners, home health agency, a home infusion therapy supplier, a durable medical equipment supplier, or any other individual/entity determined by Secretary through guidance, which could include entities such as Specialty Pharmacies that often employ qualified nurse practitioners. These entities should be allowed to bill Medicare directly for both the drug and the administration.

We urge CMS to use its SSA § 1135 authority and make the additional emergency modifications to the incident-to regulations outlined above. These modifications are well within CMS' § 1135 authority, and they would give physicians the option of offering their patients home administration of appropriate Part B medicines and delegating some of their incident-to functions – thus making it simpler for physicians to reduce patients' contagion risks during the COVID-19 crisis. We understand that this extra flexibility will require CMS to make operational changes and encourage CMS to look at a variety of mechanisms in order to provide for access in the home during the PHE. We look forward to working with CMS on how this new flexibility can be operationalized quickly.

### **III. CMS SHOULD ALSO EXPAND THE MEDICINES COVERED IN THE HOME UNDER THE DME BENEFIT DURING THE PUBLIC HEALTH EMERGENCY.**

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<sup>25</sup> <http://www.nhia.org/resource/legislative/documents/NHIAWhitePaper-Web.pdf>

<sup>26</sup> Optum. "Home infusion therapy: Better outcomes." <https://www.optum.com/resources/library/home-infusion.html>

<sup>27</sup> National Comprehensive Care Network. "NCCN Best Practices Committee Infusion Efficiency Workgroup. Toolkit: Providing Oncology Treatments in Outpatient Setting." Revised March 31, 2020. [https://www.nccn.org/covid-19/pdf/NCCN\\_Toolkit\\_Updated\\_for\\_COVID-19.pdf](https://www.nccn.org/covid-19/pdf/NCCN_Toolkit_Updated_for_COVID-19.pdf)

<sup>28</sup> Yu A. WHYY PBS. "Penn, Jeferson expand at-home cancer treatments during COVID-19 pandemic." April 1, 2020. <https://whyy.org/articles/penn-jefferson-expand-at-home-cancer-treatments-during-covid-19-pandemic/>

<sup>29</sup> Medicare has been allowing for infusion of intravenous immune globulin therapies in the home for Part B beneficiaries through a demonstration project since 2014. <https://innovation.cms.gov/innovation-models/ivig>

<sup>30</sup> Penn Home Infusion Therapy. <https://www.pennmedicine.org/for-patients-and-visitors/find-a-program-or-service/penn-medicine-at-home/home-infusion-therapy>

<sup>31</sup> Yu A. WHYY PBS. "Penn, Jeferson expand at-home cancer treatments during COVID-19 pandemic." April 1, 2020. <https://whyy.org/articles/penn-jefferson-expand-at-home-cancer-treatments-during-covid-19-pandemic/>

CMS announced in the IFC that during the PHE it will not enforce “clinical indications for coverage” in specified national coverage determinations (NCDs) and local coverage determinations (LCDs). Specifically, the IFC explained that:

During the PHE ..., it is possible that patients receiving services for respiratory related indications will be required to receive care in unexpected settings, including the home. This may be necessary as COVID–19 and other patients are shifted across healthcare settings to accommodate an increase in patient volume.

Therefore, we are finalizing on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles), allowing for maximum flexibility for practitioners to care for their patients.<sup>32</sup>

The coverage determinations for which CMS will not enforce clinical indications for coverage during the PHE are listed in the IFC and include NCD 280.14, “Infusion Pumps,” and LCD L33794, “External Infusion Pumps.”<sup>33</sup> Currently, external infusion pumps may be covered only in conjunction with specific indications for specific drugs listed in the External Infusion Pump LCD. The IFC’s brief discussion of this exercise of enforcement discretion does not define “clinical indications for coverage” or otherwise make clear how broadly CMS is expanding coverage of external infusion pumps and drugs administered through them during the PHE. In particular, the IFC does not explain whether CMS is expanding coverage: (1) to additional indications for the drugs listed in the LCD; or (2) to additional indications for the listed drugs, plus to external infusion pumps and additional drugs that can be administered through infusion pumps but are not currently listed in the LCD.

We recommend that CMS clarify in its final rule (or in guidance) that during the PHE Medicare will cover drugs and biologicals that can safely be administered through external infusion pumps (as well as the pumps themselves) for all reasonable and necessary indications, regardless of whether the drugs and indications are currently listed in the External Infusion Pump LCD. By giving beneficiaries and their physicians more options to access drugs under Part B in the home setting, this approach could advance CMS’ goals of “provid[ing] the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health”<sup>34</sup> and “allowing for maximum flexibility for practitioners to care for their patients.”<sup>35</sup>

#### **IV. CMS SHOULD ALLOW FOR AT-HOME SPECIMEN COLLECTION DURING THE PHE TO FACILITATE ONGOING CLINICAL LABORATORY MONITORING REQUIRED FOR CERTAIN MEDICINES.**

Various drugs for Medicare beneficiaries require some level of clinical laboratory monitoring for their safe and effective use. Often, whole blood counts or other assays are required to titrate dosing or monitor for toxicity which necessitates patients having blood drawn. For instance, certain oral cancer

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<sup>32</sup> 85 Fed. Reg. at 19266.

<sup>33</sup> 85 Fed. Reg., at 19266.

<sup>34</sup> 85 Fed. Reg., at 19232.

<sup>35</sup> 85 Fed. Reg., at 19266.

medications require weekly blood testing to titrate dosing and periodic blood testing thereafter to monitor for toxicity. Patients being treated for infections with antibiotics may require follow-up blood cultures, and should avoid visits to public places (e.g., physician office, hospital outpatient department, laboratory collection site). Other frequently prescribed medications that require periodic lab work include anticonvulsants, statins, psychiatric drugs, and thyroid treatments. Current stay at home orders and increased risks to the elderly could leave many Medicare beneficiaries and their physicians facing difficult choices in how to best balance COVID-19 pandemic risks with safely maintaining access to prescribed therapies.

The IFC allows for many expanded telehealth services and for additional flexibilities for qualifying for the home health benefit during the PHE. The expansion of the definition of “homebound” should now permit expanded coverage for Part B payment for a specimen collection fee and travel allowance for a laboratory technician to draw a specimen from homebound patient.<sup>36</sup> In order to support patient care and public health, we urge CMS to make this flexibility clear either in the text or preamble of this final rule.

#### **V. CMS SHOULD ALSO CONSIDER PROVIDING ADDITIONAL PAYMENT SUPPORT FOR DRUG ADMINISTRATIONS IN PHYSICIANS’ OFFICES AND HOME SETTINGS.**

Under the flexibilities that we have requested above, home infusion providers will be reimbursed for the drugs they purchase at the average sales price (ASP) of the drug, plus 6 percent, as well as paid for the drug’s administration under the physician fee schedule (PFS). However, the current fee schedule rate may not account for administration costs associated with administering medicines in the home, such as safe and sterile transportation. To facilitate home administration, CMS should consider temporarily increasing the administration payment to make it more financially viable for these entities to provide services at home. CMS might also allow these entities to also apply for and receive funds under the provider relief fund to cover the costs of administering medicines in a patient’s home.

We also recognize that there might be some situations where drug administration in a beneficiary’s home is not the safest or best option. Physicians and infusion centers may choose to continue to administer medicines to some patients at their offices. In addition, ensuring broad capacity for drug administration in as many sites of services as possible, as determined to be appropriate by a patient’s provider, will help relieve pressure on high-acuity hospital settings in regions where COVID-19 is more prevalent. However, in order to do so safely, physicians and infusion centers may need to purchase PPE or stay open longer in order to space out patients.

On March 27<sup>th</sup>, the President signed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, which included the creation of the Provider Relief Fund.<sup>37</sup> Providers can apply for relief funds via an online portal on the HHS website. CMS should consider either a special allocation or prioritization of providers that administer Part B medicines, infusion centers, and additional entities providing home infusions to receive support from the Provider Relief Fund. These providers are helping to ease the burden on hospital systems by treating as many patients as possible in their offices or centers. CMS should consider prioritizing support for these providers as they continue to ease the burden on hospitals. We also ask that CMS continue assessing the adequacy of reimbursement for providers and patient access to drug therapies on an ongoing basis.

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<sup>36</sup> Social Security Act § 1833(h)(3)

<sup>37</sup> <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf>

In addition, should CMS provide physician practices with the new flexibilities we have requested above and refer patients to qualified entities to purchase and administer Part B medicines in beneficiaries' homes, those practices may experience a loss of revenue. CMS should consider prioritizing these providers when approving applications for grants and funding to ensure that after the COVID-19 PHE, these providers are able to resume serving their patients in the office or center-setting.

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We greatly appreciate the proactive actions HHS has taken to support patient access to needed services and treatments during the current, unprecedented public health emergency, including reforms provided in the current IFC that recognize the importance of protecting beneficiary access to Part B medicines. We urge HHS to build on these reforms and use its emergency authority to allow additional entities to administer Part B medicines and perform specimen collection in patient's homes for the duration of the COVID-19 public health emergency.

PhRMA and our member companies are committed to doing all we can to help address the COVID-19 public health emergency. We would be pleased to provide any additional information that is needed regarding our comments.

Sincerely,



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Randy Burkholder  
Vice President, Policy & Research



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Kathleen Verb  
Director, Policy, Research & Membership



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Amanda Pezalla  
Assistant General Counsel, Law