The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G 200
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May 7, 2020

Dear Administrator Verma,

The undersigned stakeholders appreciate the efforts of the Trump Administration and Centers for Medicare & Medicaid Services (CMS) to provide additional flexibilities to providers to ensure that patients receive medically necessary treatments, including administration of devices, drugs and biologicals, during the public health emergency. In particular, the Administration has provided flexibilities for Medicare beneficiaries who are unable to receive treatment in the hospital outpatient setting, including Ambulatory Surgical Centers, due to risk of exposure to the COVID-19 infection. As part of these flexibilities, we write to urge CMS to utilize its authority under Section 1135(b)(5) of the Social Security Act (Act)to extend transitional pass-through status for qualifying devices, drugs, and biologicals under Section 1833(t)(6)(C) of the Act. This extension is necessary to promote adequate access to and reimbursement for innovative therapies during and after the COVID-19 public health emergency that was declared by Secretary Azar on January 31, 2020.

The extension will provide Medicare beneficiaries enhanced access to certain products that otherwise would have been policy packaged in the hospital outpatient setting, including Ambulatory Surgical Centers. Further, the extension will allow CMS to continue to separately reimburse products that would have been policy packaged providing the agency with additional claims data from which the agency can make better and more informed packaging decisions. The Public Health Emergency has and will likely continue to distort treatment patterns in the outpatient setting for scheduled procedures. Even when scheduled procedures resume, utilization of the otherwise packaged products will be lower. As such, the agency will not gain a true and accurate assessment of the clinical utility and cost impact of the products from its limited claims data that resulted from fewer procedures being performed during and after the Public Health Emergency. Without this certainty, the undersigned are concerned that CMS's claims data may lead to inaccurate policy conclusions related to the products.

We believe that the agency has the authority to extend the transistional pass-through period based on past precedent and under existing authority. For example, in the past CMS has extended temporary payment methodologies for other types of delays such as regulatory or production disruptions. Additionally, during the emergency period, Section 1135(b)(5) of the

Act gives CMS clear authority to extend or otherwise modify timetables and deadlines for the performance of required activities with respect to health care items and services furnished by health care providers, in order to promote sufficient access to such items and services and to protect health care providers who are unable to meet certain otherwise applicable requirements in light of the emergency. We believe that extending the pass-through status period would further the interests underlying this Section.

Congress created pass-through status to encourage the development of and access to innovative new therapies. Specifically, CMS has implemented the pass-through payment status for qualifying devices, drugs, and biologicals during the initial 3-year period when the therapies are first made available for payment under the Medicare Hospital Outpatient Prospective Payment System. As CMS has repeatedly explained, "[t]he intent of pass-through payment, as implemented at [42 C.F.R. §§ 419.64–66,] is to facilitate access for Medicare beneficiaries to the advantages of new and truly innovative devices, drugs, and biologicals by allowing for adequate payment for these new devices, drugs, and biologicals while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate."[1] In other words, pass-through status is intended to encourage adequate access to care and reimbursement for truly innovative new devices, drugs, and biologicals because, in the absence of pass-through status, there is not sufficient claims data to appropriately reimburse innovative new therapies, which significantly discourages adoption of them. We believe that the disruption in treatment patterns caused by the Public Health Emergency does not provide adequate data for CMS to comply with the intent of the pass-through policy.

As reverberations of the COVID-19 pandemic extend throughout the health care economy, the intent of pass-through status has been compromised by the public health emergency and necessary claims data cannot be collected. Temporarily extending the pass-through period is necessary because the vast majority of therapies that currently qualify for pass-through status are furnished in association with non-emergent procedures. Yet, throughout the country, virtually all non-emergent and non-trauma medical procedures have been brought to a standstill.[2] As a practical matter, the COVID-19 public health emergency has therefore halted access to pass-through devices, drugs, and biologicals. This creates serious concerns about beneficiary access to and adequate provider reimbursement for pass-through therapies during the emergency period. It also means that the statutory objective of pass-through status is significantly compromised: Because no claims are being generated for the vast majority of pass-through therapies, CMS cannot use the pass-through period to develop appropriate Ambulatory Payment Classification-based reimbursement (as it normally would, if elective procedures still were occurring).

Under the circumstances, we urge CMS to extend the statutory pass-through period–for all products that have pass-through status as of April 1, 2020 and that would be policy packaged because they are "integral to" a procedure in both the HOPD and ASC settings for the duration

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1 CMS, Process and Information Required to Apply for Pass-Through Payment 1 (2019), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.

2 *Cf.* CMS, CMS Adult Elective Surgery and Procedure Recommendations 1–2 (Apr. 7, 2020) (recommending delaying non-emergent treatment).

of the public health national emergency. In other words, no product's pass- through status should expire under the public health emergency. Second, the agency should extend each policy packaged product's pass-through at least one year from the date the Secretary announces the end of the public health emergency. In doing so, the agency will provide at least three full years of claims data under normal market conditions from which to make policy decisions.

Thank you for your consideration. If you request more information or have any questions, please contact Nancey McCann at nmccann@ascrs.org.

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