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December 29, 2020

The Honorable Seema Verma Administrator Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W., Room 445-G Washington, DC 20201

Re: CMS-1736-FC; Medicare Program; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physicianowned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model, and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19); (Vol. 85, No. 249), December 29, 2020.

Dear Administrator Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system final rule with comment period (FC) for calendar year (CY) 2021. The AHA's comments focus on the interim Ambulatory Payment Classification (APC) assignments and payment rates for two new Current Procedural Terminology (CPT) codes that describe the administration of the Pfizer-BioNTech SARS-CoV-2 vaccine.

In the FC, CMS assigns CPT code 0001A, administration of the first dose of the COVID-19 vaccine, to New Technology APC 1492 with a payment rate of \$15.50. Additionally, it assigns CPT code 0002A, administration of the second dose of the COVID-19 vaccine,



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to New Technology APC 1493 with a payment rate of \$25.50. Thus, the total payment for administering both doses of the COVID-19 vaccine will be \$41.

We disagree with CMS' interim APC assignments of COVID-19 vaccine administration services to these New Technology APCs because they are inconsistent with longstanding CMS policy. Specifically, in the FC, CMS states, "For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs." (Emphasis added). However, CMS does not lack sufficient clinical information and cost data for the administration of the COVID-19 vaccines; indeed, it has the information it needs to assign these codes to an appropriate clinical APC. This is because the COVID-19 vaccine administration service is *clinically* similar to administration of influenza, pneumococcal and hepatitis B vaccines, as these all involve an uncomplicated intramuscular injection of the vaccine. In addition, CMS clearly has indications of the cost of the vaccines, as it stated in the recent CMS-9912-IFCⁱ, "We anticipate that payment rates for the administration of other Part B preventive vaccines and related services, such as the flu and pneumococcal vaccines, would serve to inform the payment rates for administration of COVID-19 vaccines." For many years, CMS has assigned these other three vaccine administration services to APC 5691, Level 1 Drug Administration, which has a 2021 OPPS payment rate of \$40.

Moreover, CMS understands that there are additional costs for the COVID-19 vaccine. In the same IFC the agency states, "Therefore, as soon as practicable after the authorization or licensure of each COVID-19 vaccine product by FDA, we will announce the interim coding and a payment rate for its administration (or, in the case of the OPPS, an APC assignment for each vaccine product's administration code), taking into consideration any product-specific costs or considerations involved in furnishing the service. Such consideration may be necessary, specifically for COVID-19 vaccines in the context of the pandemic, in order to ensure that health care providers can offer prompt access to vaccination for a large number of people as quickly as possible." (Emphasis added). As CMS is aware, there are, in fact, far greater resources involved in COVID-19 vaccine administration than for these other three vaccines. This includes requirements for cold storage, higher levels of personal protective equipment, more time spent on education about the vaccines and potential side effects, greater reporting requirements to jurisdictional public health authorities and the many requirements in the Centers for Disease Control and Prevention's COVID-19 Vaccine Program Provider Agreement, with which hospitals must comply.

With these additional resource costs, the assignment of the COVID-19 vaccine administration codes to New Technology APCs 1492 and 1493, at a 2021 rate of \$15.50 and \$25.50 respectively, will clearly result in a significant Medicare underpayment. Moreover, given that the administration of the COVID-19 vaccine involves greater resources than the three other vaccines assigned to APC 5691 with a 2021 APC rate of

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\$40, we also believe assignment to this APC would result in a significant Medicare underpayment. At a time when America's hospitals are stretched incredibly thin and in light of the devastating impact that the COVID-19 pandemic has had on hospital and health system financial health, adequate payment for this vaccine is critical. As such, the AHA recommends that each of the COVID-19 vaccine administration codes be assigned to APC 5692, Level 2 Drug Administration, with a 2021 rate of \$61.97.

We appreciate your consideration of these issues. Please contact me if you have questions or feel free to have a member of your team contact Roslyne Schulman, director for policy, at <u>rschulman@aha.org.</u>

Sincerely,

/s/

Ashley Thompson Senior Vice President Public Policy Analysis & Development

ⁱ <u>CMS-9912-IFC</u> is the interim final rule with request for comments (IFC) which discusses CMS's implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136), which established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID-19) vaccine and its administration.