



HEART FAILURE SOCIETY OF AMERICA

Phone 301-312-8635 • 9211 Corporate Blvd., Suite 270, Rockville, MD 20850

October 5, 2020

Seema Verma, MPH  
Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1734-P  
Baltimore, MD 21244-8016

**RE: RE: CY 2021 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS-1736-P)**

*Submitted electronically via regulations.gov*

Dear Administrator Verma:

On behalf of the Heart Failure Society of America (HFSA), we are writing to provide input on the Centers for Medicare and Medicaid Services (CMS) calendar year (CY) 2021 Outpatient Prospective Payment System (OPPS) proposed rule. The vision of the Heart Failure Society of America is to significantly reduce the burden of heart failure. HFSA is a multidisciplinary organization working to improve and expand heart failure care through collaboration, education, research, innovation, and advocacy.

We appreciate the opportunity to comment on this proposed rule. Our comments focus on the Agency's proposal to eliminate the Inpatient Only (IPO) list and related 2 Midnight Rule implications.

### **Services That Will Be Paid Only as Inpatient Services**

In CY 2000, CMS established the IPO list to designate services that should be provided only in the inpatient setting, and thus, a list of services that are ineligible for payment in the hospital outpatient setting. Since the establishment of the IPO list, CMS has engaged in regular reviews of the list to determine whether circumstances provide for the delivery of the service in the outpatient setting. In order to determine whether that would be appropriate, CMS utilizes the following criteria:

- *Most outpatient departments are equipped to provide the services to the Medicare population.*
- *The simplest procedure described by the code may be performed in most outpatient departments.*
- *The procedure is related to codes that CMS has already removed from the inpatient list.*
- *A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.*
- *A determination is made that the procedure can be appropriately and safely performed in an ASC and is on the list of approved ASC procedures or has been proposed by us for addition to the ASC list.*



As part of CY 2021 rulemaking, CMS proposes to:

- Implement a policy eliminating the IPO list over the next three years
- Remove 266 musculoskeletal services from the IPO list for CY 2021

In addition, CMS seeks specific comment on:

- Whether there are other services that should be candidates for removal from the IPO list in the near term
- The order of removal for additional clinical families and/or specific services for CY 2022 and CY 2023 rulemaking
- Whether it should restructure or create any new ambulatory payment classifications (APCs) to facilitate removal of some procedures from the IPO list

HFSA is concerned that CMS proposal is unnecessarily rushed, does not provide adequate safeguards to protect patients from third parties that could adversely influence patient-physician decision-making, and takes a categorical rather than a clinically-based approach to removing services from the IPO list. The current criteria utilized by CMS for analyzing whether a service should be removed from the IPO list are reasonable and flexible. We do not believe that the current standard is a barrier to performing procedures on an outpatient basis when it is deemed safe for patients and hospitals are equipped to perform the procedures on an outpatient basis. Conversely, we are concerned that because payers tend to reimburse at lower rates for procedures performed in the outpatient setting that there will be undue pressure placed on providers to move cases into the outpatient setting when that is not in the best interest of the patient. While we agree with CMS that a physician will use her or his best judgment based on the available information to determine the most appropriate and efficient site-of-service for the patient it is unquestionable that such decisions are not made in a vacuum, and payer practices can inappropriately attempt to influence these decisions. This can also sometimes lead to denial of coverage for services, exposing patients to unnecessary financial liabilities. The IPO list currently provides patients (and physicians) with an important protection and removing that guardrail without even a discussion of these issues we believe would be ill-advised and potentially increase rather than decrease administrative burden.

For these reasons, ***HFSA recommends that CMS rescind its proposal to remove all procedures from the IPO list and instead continue to review and analyze procedures for removal using its current criteria, allowing for decisions to be made on case-by-case basis with the input of patients, physician specialties, and other stakeholders.*** The most important way to approach these policies is to keep patients at the center of these discussions. We are concerned that by categorically eliminating the protection of the IPO list, cost drivers will overwhelm the system, when our primary focus should be on what is best for the patient.

We also believe that CMS' proposal lacks a critical component: quality measurement. We believe that the IPO list has been a key patient protection over the years. If CMS is planning to allow for the provision of a vast number of services in the outpatient setting, the policy should be implemented with a clear vision for integrated quality measurement to ensure that patient health outcomes are not compromised by the new policy. In the event that CMS still implements the elimination of the IPO list, ***HFSA urges CMS to incorporate quality measures that provide adequate protection and an early warning system if the move to the outpatient setting has compromised patient outcomes, including patient safety and satisfaction.*** While the system might realize a reduction in "resource use" from decreased reimbursements in the outpatient setting compared to the inpatient setting, it could be quickly outweighed by the impact of increased re-hospitalization rates.

Again, HFSA urges CMS to take a cautious approach to removing services from the IPO list and continue to evaluate services on a code level basis.

### **Proposed Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2021 and Subsequent Years**

In this proposed rule, CMS reviews its policies related to the 2-midnight rule for determining when an inpatient admission is considered “reasonable and necessary” for Part A payment. As such, CMS restated that it has established a policy with “a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for inpatient hospital admission and payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation.”

It has also been CMS policy that admissions for services on the Inpatient Only list would be considered appropriate, as an exception to the 2-midnight policy, and thus, protected from site-of-service reviews. However, now that CMS has proposed the elimination of the IPO list, this exception would no longer be relevant. As procedures are removed from the IPO list, CMS has proposed a 2-year exemption from site-of-service denials, Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIO) referrals to Recovery Audit Contractors (RACs), and RAC reviews for “patient status” for procedures removed from the IPO list.

Given the concerns expressed above, we believe that any attempts to eliminate the IPO list must be accompanied with steps to protect patients from inappropriate payer behavior. We appreciate the 2 year exemption from site of service reviews for services removed from the IPO. However, given the scope and gravity of the changes proposed by CMS, ***the HFSA urges CMS to extend the exception from site-of-service reviews for services removed from the IPO list from 2 years to 4 years to allow for full quality and safety analysis.*** We believe this will allow an appropriate amount of time for clinician/patient decision-making to take place free of concern about inappropriate audits or payer behaviors, while providing sufficient time to understand the quality implications of resulting changes in practice. Such an extension will result in a more stable system and ensure that it is truly the judgment of the clinician, shared decision-making with the patient, high quality outcomes and thoughtful clinical pathways driving site-of-service selection.

Thank you for your consideration of these views. If you have questions or require additional information, please contact John Barnes, HFSA Chief Executive Officer, at [jbarnes@hfsa.org](mailto:jbarnes@hfsa.org).

Sincerely,



Biykem Bozkurt, MD, PhD, FHFA  
President  
The Heart Failure Society of America