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Submitted electronically via www.regulations.gov.

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-1772-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; etc.

Dear Administrator Brooks-LaSure:

The Conference of Boston Teaching Hospitals, on behalf of our 12 member hospitals, appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) proposed rule for calendar year (CY) 2023.

340B

Following the Supreme Court's decision in *American Hospital Association v. Becerra*, we were disappointed to see the inclusion of the continued ASP -22.5% cut to reimbursement for 340B drugs. We acknowledge the timing of the decision was complicated for the agency, and are grateful that CMS expects reimbursement in CY 2023 to be ASP +6% for 340B drugs. We believe these cuts were inappropriately steep, and impeded hospitals' and other health care providers' ability to reduce the price of drugs for low-income patients and expand the services available to vulnerable populations they serve. COBTH member hospitals use their 340B savings to provide free care, offer free vaccinations, and make other investments in the health of their communities. We are pleased that 340B reimbursement is expected to be restored in the coming year.

However, we are deeply concerned about CMS's application of the increased 340B reimbursement in the absence of accurate underlying estimates of 340B spending. Since 2018, CMS has underestimated 340B cuts and failed to apply an accurate amount of savings to other areas of OPPS reimbursement. Due to the expected increase in 340B reimbursement, the agency proposes a $1.96 billion adjustment to outpatient service payments. However, CMS continues to rely on inaccurate calculations made in 2018 that undercount the reductions of 340B reimbursement. Instead of applying the proposed -4.04% adjustment to outpatient payments, we urge the agency to only apply a -3.2% adjustment, which is equal to the increase in non-drug services from 2020-2022.

We also must urge CMS to promptly repay 340B hospitals the difference between ASP +6% and what they actually received from drug claims from 2018-2022 as a result of the unlawful

reimbursement cuts in effect during this time period. It is also critical that hospitals are held harmless from any potential negative ramifications of CMS's efforts to rectify its unlawful reimbursement cuts, and the agency should ensure that no funds are recouped based on increased non-340B reimbursements that were received during the duration of the policy.

Organ Acquisition

We appreciate CMS's decision to defer rulemaking on organ acquisition following the response to its proposal in the FY22 IPPS proposed rule. COBTH had serious concerns that the proposal in that rule would have created an enormous administrative burden for transplant programs, ultimately disincentivizing transplants and making transplant organs harder to access for the many patients in need. In the CY23 OPPS rule, the agency requests information on possible changes to its organ counting methodology, including limiting counted organs to only organs transplanted into Medicare beneficiaries in the transplanting hospital.

While we appreciate CMS's decision not to require transplant programs to track the insurance status of those who receive transplant organs outside of that hospital, we are concerned that removing organs transferred to another program from both the numerator and denominator may result in under-reimbursement for transplant services. Additionally, it appears this proposal would eliminate reimbursement for "unusable" organs that are unable to be transplanted at all, despite the costs associated with the attempts to use those organs for transplant.

While we appreciate the agency's mention of "revenue offsets," we would need more information to assess whether this is adequate to ensure our programs would be properly reimbursed. Overall, we believe the proposal from CMS would negatively impact centralized donor recovery center partnerships between Organ Procurement Organizations and transplant centers, which have demonstrated ability to reduce transplant costs, improve donor care, and increase organ yield.

We also provided comments last year expressing concern that the previously proposed policies would disproportionately impact children's hospitals, where many procured organs are transplanted into Medicaid beneficiaries. We think it is important to ensure that children's hospitals that perform transplants are adequately reimbursed for these critical services, which may require an alternate counting methodology.

Overall, we believe Medicare's existing organ acquisition cost policy serves to streamline and incentivize organ procurement and transplantation. Any proposal with the potential to decrease the availability of donor organs will not only harm patients, but is also likely to increase long-term costs to the Medicare program. We urge CMS to carefully consider changes to the organ acquisition policy and ensure that any changes will not decrease the availability of transplant organs.

Remotely Furnished Behavioral Health Services

We strongly support CMS's proposal to establish an OPPS payment for remotely furnished behavioral health services for Medicare beneficiaries who are in their homes. Our members have been able to successfully provide these services to Medicare beneficiaries due to the waivers provided under the COVID-19 public health emergency, and we are grateful that CMS proposes making them permanently available to Medicare recipients. This proposal will give our providers

the certainty they need to continue scheduling these types of appointments for patients, which are both convenient and effective for providers and patients alike.

However, we are seriously concerned about CMS's proposal to reimburse these services at the physician fee schedule facility rate, rather than at the full OPPS rate. CMS argues that hospitals are not incurring all of the costs associated with in-person services when providing remote services to patients who are in their homes. COBTH disagrees with this assertion, and urges CMS to reconsider the costs associated with providing behavioral telehealth services. First of all, fixed practice costs do not go away because a patient is seen via telehealth, and considerable staff time and resources are still necessary to make a telehealth visit run smoothly, including scheduling and setting up the appointment, assisting patients with connecting to the appointment, screening patients, making referrals and scheduling follow ups, and more. Recognizing these costs, we request that CMS reimburse remotely furnished behavioral health at the full OPPS rate.

We are also deeply concerned about CMS proposed requirement that an in-person visit be furnished within six months of the first remote mental health service and continually every 12 months after the public health emergency ends. In addition to the logistical hurdles for patients and providers, we are incredibly concerned that this requirement perpetuates stigma related to receiving mental health care. We encourage CMS not to finalize the in-person requirements. If the agency insists on moving forward, we encourage the implementation of broad exception criteria based on clinical discretion, as well as an expansive view of the types of in-person visits that can meet the stated requirements.

Finally, we appreciate CMS's proposal to allow audio-only remote behavioral health visits based on individual patient's technology limitations, abilities, or preferences. The availability of audio-only telehealth services is critical to ensuring access to care for older and lower-income Medicare beneficiaries that may not have the device or broadband access required to furnish a successful two-way audio/video visit. We urge CMS to finalize this proposal.

Direct Supervision

CMS requests comment on the possibility of continuing to allow direct supervision of certain cardiac and pulmonary rehabilitation services via interactive communications technology. COBTH member hospitals have successfully used the flexibility provided by CMS to safely and effectively provide direct supervision to physician trainees providing a variety of health care services. While we agree that virtual supervision may not be appropriate in every instance, we do believe there are services, such as cardiac and pulmonary rehabilitation, that can be appropriately supervised via interactive audio-video technology. Ultimately, the decision about how to safely provide direct supervision can and should be made at the discretion of the supervisor. We encourage CMS to continue to allow virtual direct supervision beyond the end of the PHE for these services.

Thank you for your consideration of our comments. COBTH's member hospitals are also members of the Association of American Medical Colleges (AAMC) and strongly support the in-depth comments submitted by AAMC on behalf of the nation's academic medical centers and teaching hospitals. Please do not hesitate to be in touch with any questions or if we can provide additional information on these or other matters.

Sincerely,

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