Business Group on Health

October 2, 2020

*Submitted electronically via: www.regulations.gov*

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1736-P
P.O. Box 8013
Baltimore, MD 21244-1850

**Re: CMS-1736-P – 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; and Physician-Owned Hospitals**

Dear Sir or Madam:

Business Group on Health (The Business Group) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS's) notice of proposed rulemaking revising the Medicare hospital outpatient prospective payment and ambulatory surgical center payment systems and other issues.

The Business Group represents a network of today's largest and most progressive employers, including 74 Fortune 100 companies, providing health coverage for 60 million workers, retirees and their families in 200 countries.

As the largest single payer for health care in the U.S., Medicare must continue to lead the way and partner with private sector payors to drive delivery transformation away from a dysfunctional fee-for-service (FFS) system toward alternative payment models that will reduce overall costs and improve health outcomes, particularly successful

20 F Street, NW
Suite 200
Washington, DC 20001

202-558-3000
info@businessgrouphealth.org

Visit us at:
www. businessgrouphealth.org

models managing the total cost of care, improving population health, and keeping people well.

The Business Group is encouraged by CMS' continued move toward these goals. We also support CMS' efforts to make changes to the fee-for-service system now to improve quality and keep from further exacerbating Medicare's fiscal problems that could lead to increased taxes for employers and employees. We support the CMS push to optimize the delivery system by steering it via payment mechanisms, transforming health care delivery and encouraging improvements in quality and transparency.

Specific to the proposed rule, the Business Group is commenting on proposed changes to site-of-service, adding prior authorization requirements for certain procedures, transforming care delivery and quality and transparency provisions.

Site-of-Service

Our members are actively engaged with providers in improving health care delivery, either via direct contracting or partnering with health plan administrators. One critical element is assuring that payment policy and plan design encourage the use of lower cost, high quality sites of care for services where appropriate. We are encouraged that CMS is building on its previous efforts to address site-of-service in the proposed rule by:

- Phasing out the Inpatient Only (IPO) List over a 3-year period (beginning in calendar year (CY) 2021). The IPO list encourages providers to perform certain procedures on an inpatient basis as a default, but also allows providers to determine the appropriate setting (inpatient or outpatient). This change will ensure maximum availability of services to beneficiaries in the outpatient setting, where evidence supports and advances in surgical care and medical technology make possible, as determined appropriate by the physician and in accordance with state and local regulations, accreditation and CMS quality and safety requirements:
    - Beginning in CY 2021 with the removal of nearly 300 musculoskeletal-related services and eventually transitioning to all IPO procedures by 2024.
    - However, we strongly recommend that CMS carefully evaluate the impact on safety, quality, appropriateness, utilization, and costs in the first year and, if necessary, reevaluate the timetable and addition of other procedures if warranted.

While the Business Group strongly supports care at the most appropriate site based upon the clinical needs of the patient, we have concerns about the relationship between very high level of physician ownership of ASCs (according to studies upwards of 90%) and the impact on volume and unnecessary care. Studies, by Dr. Jean M. Mitchell of Georgetown, have demonstrated that physician ownership of specialty hospitals and ASCs could influence physician practice patterns. For example, a 2010 study of outpatient orthopedic surgeries showed that the, "likelihood of having carpal tunnel repair was 54% to 129% higher for patients of surgeon owners compared with surgeon nonowners. For rotator cuff repair, the adjusted odds ratios of having surgery were 33% to 100% higher for patients treated by physician owners." Therefore, we recommend CMS closely monitor the above procedures for any statistically significant increases in volume that suggest higher levels of unnecessary care and to guard against fraud, waste and abuse. Nevertheless, as technology and advances in surgical practice make it more feasible to safely perform more procedures on an outpatient basis, we support the following:

- Permitting Medicare to pay for an expanded set of procedures at ambulatory surgery centers (ASCs), typically a lower cost site of care, if they do not pose significant safety risks. Specific procedures mentioned in the proposed rule include total hip arthroplasty (THA), vaginal colpopexy, transcervical uterine fibroid ablation, intravascular lithotripsy procedure and others.
    - CMS should closely monitor and evaluate the experience with the first set of procedures to determine safety and efficacy and, if appropriate, take steps towards expanding the list of eleven procedures to the potential 270 surgery or surgery-like codes meeting CMS criteria.

For aforementioned reasons, we are concerned with CMS' proposal to permit physician-owned hospitals with high Medicaid populations or in rural areas to expand beyond limits imposed by the ACA, which do not permit facilities to increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010. We urge CMS to reconsider its proposal to allow these facilities to expand.

- To the extent that CMS permits expansion, at the very least we recommend close monitoring of physician-owned hospitals for increases in unnecessary care.

Prior Authorization

Employers, working with their health plans and other partners, regularly review and mine claims data for inappropriate utilization, misaligned incentives, and relative benefit outcomes. We are encouraged that the CMS, as a result of its review of 10 years of claims data, identified two procedures, Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators, where there has been a dramatic growth in volume that could be exacerbated by previous Medicare payment changes.

According to our most recent survey, 90% of respondents indicated that Musculoskeletal issues are a top condition driving health care costs and trend. Better public and private sector alignment on payment issues could reduce inappropriate use or misuse of these procedures. Therefore, the Business Group strongly supports:

- Adding a prior authorization requirement for these two procedures. We also encourage the CMS to continue to regularly monitor and review claims data for other procedures where dramatic growth in volume may suggest unnecessary utilization warranting prior authorization.

Transforming Delivery

The Business Group supports CMS' efforts to transform delivery by reducing or eliminating unnecessary or modifying burdensome requirements for providers. One way to do that is to relax direct supervision requirements by physicians or non-physician providers (NPPs) such as clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, or certified nurse-midwives where quality and safety are not at issue. This change should free up providers and NPPs to treat other patients requiring more extensive care and monitoring. We support CMS' proposal to:

- Beginning on or after January 1, 2021 permitting direct supervision of cardiac rehabilitation, intensive cardiac rehabilitation, and pulmonary rehabilitation services via virtual presence of the physician through audio/video real-time communications technology subject to the clinical judgment of the supervising physician. This change is likely to increase access to rehabilitation services for patients by reducing the burden on physicians to be physically present.
- Permanently extend beyond the Public Health Emergency (PHE) the permission to allow for general supervision of Non-Surgical Extended Duration Therapeutic

Services (NSEDTS), rather than direct supervision, which is the default requirement.

Direct supervision requires a physician or NPP, to be immediately available to furnish assistance and direction throughout the performance of a service whereas general supervision requires a service be furnished under a physician's or NPP overall direction and control, but their physical presence is not required during the performance of the actual service.

Typically, these services have a significant monitoring component that can extend for a lengthy period of time, are not surgical, and have a low risk of complications after the assessment at the beginning of the service. For example, an intravenous infusion for therapy/diagnosis; initiation of prolonged infusion (more than 8 hours), requiring use of portable or implantable pump, would be an example of a NSEDTS. More examples are available here. As noted by CMS, to the extent necessary, hospitals can transition to direct supervision for any part of a NSEDTS when the practitioners administering the medical procedures decide that it is appropriate to do so.

Quality/Transparency

Business Group on Health believes that payers, patients and consumers need good, reliable information about the quality of health care providers and services, along with the prices they would pay and the total cost of care under their health plan coverage. CMS stewards a trove of Medicare data on quality of both providers and facilities, including for outpatient services. We applaud efforts by the CMS to make this data available in a user-friendly way to the public while at the same time promoting meaningful measures, reducing the administrative burden, and generally streamlining of information for comparability. Business Group on Health participates in the Core Measures Quality Collaborative, which the CMS also participates in, and the NQF's Measures Application Partnership, which advises the CMS, both of which share these same goals. Therefore, the Business Group supports the following provisions in the proposed rule:

- CMS' proposal to continue the 2% reduction in payment for failure to meet hospital outpatient quality reporting requirements.
- While there are no proposed changes in reporting requirements for 2021 for 2023 payment determinations, we support the CMS' efforts to increase focus on meaningful measures while reducing the administrative burden and aligning

reporting requirements among programs in the Outpatient Quality Reporting program and the Ambulatory Surgery Center Quality Reporting Program. We believe that the recommendations of both CMQC and the MAP offer useful guidance to CMS in this regard. As more services are performed in ASCs, it will be particularly important that Medicare and other consumers have better information on the quality of care at these facilities.

- Changes in the hospital star quality ratings program beginning in 2021, that simplify the methodology for calculating ratings, which also increase the predictability and comparability of hospitals, making them more useful to consumers. At the same time the changes reduce the administrative burden for hospitals and improve their understanding of how ratings are determined.
- Efforts to better risk adjust ratings for dual eligible patients (those in both Medicare and Medicaid) and efforts to increase the comparability of ratings in the FFS program with that of the Medicare Advantage program.
- Extension of the rating system to Veterans Administration hospitals, beginning in 2023, and Critical Access Hospitals that have sufficient volume. All of these changes will improve the comparability of ratings for consumers and reduce incentives for hospitals to serve dual eligible patients. These ratings are also useful for private payers and consumers in assessing hospital quality.

Thank you for considering our comments and recommendations. Please feel free to contact me (kelsay@businessgrouphealth.org), Steve Wojcik (wojcik@businessgrouphealth.org), the Business Group's Vice President of Public Policy or Matthew Sonduck (sonduck@businessgrouphealth.org), Policy Associate to discuss.

Sincerely,

Ellen Kelsay
President and CEO