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CMS Continues to Consider Organ Acquisition Cost Rule Changes

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In response to the Centers for Medicare & Medicaid Services' (CMS's) proposed changes to Medicare's organ acquisition payment policies proffered in the Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (Proposed Rule), briefly discussed in our previous article here, stakeholders undoubtedly had much to say. After receiving more than 6,500 public comments on the Proposed Rule, CMS recently issued some portions of the Proposed Rule in their final form. However, the provisions related to organ acquisition costs remain on hold and under further review. Organ Procurement Organizations (OPOs), transplant and donor hospitals, and other key stakeholders provided substantial feedback during the comment period, and based on the number and nature of the comments submitted, CMS has opted to "address public comments associated with these issues in future rulemaking" to consider these issues more closely. Some of the more significant concerns as expressed in the comments are highlighted below.

Proposed Definitions – Inclusion of VCAs

Many commenters expressed concern that the definition of "organ" in the Proposed Rule unnecessarily excludes vascular composite allografts (VCAs). VCAs are transplants involving transplantation of multiple tissues such as muscle, bone, nerve, and skin as a functional unit, such as a hand or face. In procuring VCAs, OPOs accrue costs similar to those accrued when procuring traditional organs. VCA transplants can meaningfully improve the quality of life and significantly advance positive patient outcomes, and for this reason, many stakeholders acknowledged the importance of including VCAs in the definition. Moreover, in 2014, the Organ Procurement and Transplantation Network (OPTN) added VCAs to its definition of "organ," in order to reflect the clinical advances in transplantation. Accordingly, in order to continue support for and encouragement of these critical advances in transplantation, many stakeholders have urged CMS to include VCAs as "organs," thereby facilitating greater patient access to VCA transplantation. CMS may reconsider the definition of "organ," particularly because including VCAs would likely further support and increase organ donation and transplantation.

Reporting of Recipient/Payer Information

In the Proposed Rule, CMS cited recent technological advancements and improved organ recipient tracking abilities when proposing that OPOs should report the identity of organ recipients and their respective payer information. In short, CMS proffered that because OPOs now have greater access to information regarding where and to whom an organ goes, OPOs should bear the responsibility of reporting this information for Medicare purposes. This policy is meant to result in a more accurate accounting, with Medicare only paying for organs that are ultimately transplanted into Medicare beneficiaries. While most commenters generally support CMS's goal of more accurate Medicare reimbursement in this regard, many stakeholders expressed concerns with this portion of the Rule as related to privacy, accuracy of reporting, and unnecessary increases in administrative burdens.

More specifically, although OPOs may be able to access transplant recipient information in the national data tracking system, requiring an OPO to access, maintain, and report patient information for Medicare reimbursement purposes without express authorization from the patient raises patient privacy concerns. For example, some OPOs stressed that OPOs do not provide patient care in the traditional sense and should not

be responsible for reporting patient and payer information. OPOs obtain authorization for donation from deceased donors and procure and transport organs for transplantation but do not provide care to patients. With regard to patient privacy, OPOs are not "covered entities" or "business associates" under the Health Insurance Portability and Accountability Act (HIPAA). (*See* OPTN guidance.) However, OPOs are allowed to access donor information – without first acquiring express authorization – for the purposes of determining donor suitability and performing their functions as an OPO via an express exception within HIPAA. Notably, there is no similar express exception for OPOs to access transplant recipient information, particularly for the purpose of determining payer information. Some OPOs expressed concern that, even if the HIPAA exception were interpreted broadly enough to allow OPOs to access patient information for this purpose, state laws may apply that bear on this access and redisclosure and should also be considered by CMS when promulgating these policies.

Moreover, many OPOs pointed out the increased administrative burden that supplying this information would likely impose, in addition to potential challenges OPOs may face in confirming whether and to what extent a recipient is covered by Medicare. Some OPOs suggested alternative, less burdensome, and more reliable reporting sources for this information, including obtaining this information from transplant hospitals where the patients obtain health care. In addition, and in anticipation of this administrative burden, some transplant hospitals and the American Society of Transplant Surgeons strongly urged CMS to reconsider this policy. As CMS contemplates potential revisions to the organ acquisition payment policies, this one may be more closely reviewed and amended.

Costs Related to Donor Transportation

The Proposed Rule also clarifies that costs incurred related to transportation of a deceased donor before or after organ procurement are not included in Medicare's organ acquisition costs. Notably, 42 U.S.C. § 273(b)(3)(F) requires OPOs to provide and arrange for transportation of donated *organs* to transplant hospitals, and it does not prohibit transportation of the donor as an allowable cost. Many OPOs emphasized the significant cost savings achieved in cases in which the OPO is able to transport the donor from a donor hospital to an off-site surgical recovery center. Additionally, in certain cases, the efficiency of recovery is greatly improved by transporting the donor to another recovery site. Some OPOs emphasized that, as the process of transferring donors continues to be refined, the savings is expected to grow. Thus, CMS may reconsider developing payment policies that do not create disincentives for the transferring of donors, particularly in that these transfers may enhance the donation and transplantation process while simultaneously saving additional costs.

Key Takeaways

The issues we highlight in this article are just a few of the many raised by stakeholders with regard to CMS's proposed organ acquisition payment policies. As discussed in previous articles here and here, the national organ donation and transplantation system continues to be reviewed, revised, and scrutinized by the federal government at various levels. As part of this process, CMS continues its quest to improve the system with the important goal of maximizing organ donation and transplantation and reducing the number of patients awaiting a life-saving transplant. However, with regard to its decision to pause finalization of the organ acquisition payment rule, CMS did not provide definitive next steps or an estimated timeframe for resolution of these issues, nor did they give any insights about which particular issues they may revisit. To that end, and due to the considerable number and nature of comments submitted in response to the Proposed Rule regarding Organ Acquisition Payment Policies, we expect that we may see additional revisions to the portions of the Proposed Rule as we have indicated herein, and possibly others.

In the interim, if stakeholders have questions about the interpretation or potential implications of any of the proposed policies, please contact Melodie Hengerer, Tenia Clayton or any member of Baker Donelson's Reimbursement team.