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Newly Proposed Rule Regarding Organ Acquisition Payment Policies

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On April 27, 2021, CMS issued its Fiscal Year 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Care Hospital (LTCH) Rates Proposed Rule (CMS-1752-P), in which it proposes several changes to organ acquisition payment policies that would enable Medicare to more accurately record and pay its share of organ acquisition costs. Sparked by OIG concerns that some organ procurement organizations (OPOs) may have billed Medicare for unallowable expenditures and similar concerns from Congress regarding OPO financial management (which are currently the subject of a House Oversight Committee investigation), CMS intends that the new policy will "allow providers and stakeholders to more easily locate and understand organ acquisition payment policy, resulting in more accurate payment based on reasonable cost principles." The proposed rule affects organ acquisition payment policies for transplant hospitals, donor hospitals, and OPOs. Notably, if the proposed rule is implemented, CMS estimates a cost savings to the Medicare trust fund of $230 million in FY 2022, $1.74 billion over five years, and $4.15 billion over ten years.

Background

Currently, Medicare's organ acquisition policy mirrors the kidney acquisition policy set forth in Section 1881 of the Social Security Act, which establishes Medicare payment for kidney transplantation, and coverage of organ procurement costs and living donor expenses. CMS's originally stated purpose for this section was to encourage kidney transplants and expand the scope of benefits to cover all reasonable expenses from preparation to post-operation recovery. Over time, Medicare has added coverage for transplantation of other non-renal organs, modeling its reimbursement for these organs after the kidney acquisition policies.

Organ Acquisition Payment Policy Proposals

In its quest to facilitate more accurate payment of Medicare's share of organ acquisition costs and to clarify these policies, CMS proposes moving all organ acquisition policies to 42 C.F.R. Part 413, subpart L, which will also include existing organ and kidney acquisition payment regulations. Further, CMS proposes the use of more consistent terminology. By way of example, CMS proposes new definitions as follows:

- The definition of "organ" under the proposed rule will differ from the definition of "organ" under the recently finalized Organ Procurement Organizations Conditions for Coverage (OPO CfCs) (42 C.F.R. 486). Under the OPO CfCs, procurement and transplantation of a pancreas counts towards an OPO's performance measurements, even if it is used for research or islet cell transplantation. The inclusion of pancreata for use by an OPO for research or islet cell transplantation is required to be considered for purposes of OPO certification or recertification by section 371(c) of the Public Health Service Act. In contrast, under the proposed organ acquisition payment regulation, an "organ" procured for research would not be reimbursable by Medicare, except where expressly required by law.

- The term "transplant hospital" (TH) will be used for hospitals that have approved organ-specific transplant programs. "Transplant program" will be used in place of "transplant center" when referring to an organ-specific transplant program within a transplant hospital.

- CMS proposes to include the definition of "organ procurement organization" that exists in § 413.200(b) and codify the definition of a hospital-based OPO (HOPO) as an OPO that is considered a department of the transplant hospital and reports its organ acquisition costs on the hospital's Medicare cost report.

Proposed Items and Services Considered Organ Acquisition Costs

CMS proposes codification of the existing policy that acquisition costs incurred from a living donor or a cadaveric donor by the donor hospital or by an OPO qualify as organ acquisition costs. To that end, CMS offers the following proposed list of organ acquisition costs, covered by Part A:

(1) tissue typing, including tissue typing furnished by independent laboratories;

(2) donor and beneficiary evaluation;

(3) other costs associated with excising organs, such as general routine and special care services provided to the donor;

(4) operating room and other inpatient ancillary services applicable to the donor;

(5) preservation and perfusion costs;

(6) Organ Procurement and Transplantation Network (OPTN) registration fees;

(7) surgeons' fees for excising cadaveric organs (currently limited to $1,250 for kidneys);

(8) transportation of the excised organ to the TH;

(9) costs of organs acquired from other hospitals or OPOs;

(10) hospital costs normally classified as outpatient costs applicable to organ excisions (services including donor and recipient tissue typing, work-up, and related services furnished prior to admission);

(11) costs of services applicable to organ excisions which are rendered by residents and interns not in approved teaching programs; and

(12) all pre-admission services applicable to organ excisions, such as laboratory, electroencephalography, and surgeons' fees for cadaveric excisions, applicable to organ excisions including the costs of physicians' services.

Additionally, certain elements related to kidney acquisition costs would also be applied to non-renal organs. The proposed rule also addresses differences in coverage for living and cadaveric donors. For example, as proposed, the rule would allow reimbursable surgeon fees in the kidney acquisition costs only with regard to cadaveric donors. CMS also proposes allowance of OPTN registration fees for transplant candidates placed on the waiting list, but any other registration fees would be deemed unnecessary and duplicative.

Proposed Calculation of Medicare's Share of Organ Acquisition Costs, Counting of Organs

The regulations at 42 C.F.R. §§ 413.202 and 413.203 represent the longstanding policy that Medicare must only share in organ and kidney acquisition costs for Medicare beneficiaries. CMS intends that the newly proposed regulation will ensure that acquisition costs are more properly allocated to the appropriate payors. Currently, Medicare's share of organ acquisition costs for transplant hospitals/HOPOs is calculated by

multiplying the total allowable organ acquisition costs by the ratio of Medicare usable organs to total usable organs reported on the hospital's Medicare cost report. For independent OPOs, Medicare calculates its share of kidney acquisition costs by multiplying the total allowable kidney acquisition costs by the ratio of Medicare usable kidneys to total usable kidneys reported on the OPO's cost report. The proposed regulations require a more accurate accounting and reporting of Medicare usable organs by considering organs that are shipped overseas or transplanted into non-Medicare beneficiaries, and the effect of improved organ recipient tracking abilities, which allow for more expeditious identification of Medicare patients.

Key Takeaways

With the promulgation of this newly proposed regulation, CMS continues to advance changes aimed at transparency and overall improvement in the organ donation and transplantation space, which has been under intense scrutiny over the past two years (*see* our earlier article here.) Transplant hospitals, donor hospitals, and OPOs should take note and use this opportunity to comment on the proposed rule while preparing to make any necessary amendments to their processes in anticipation of future compliance requirements. Comments to the proposed rule must be received by June 28, 2021.

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