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Submitted Electronically via laura.kennedy@cms.hhs.gov

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Dear Dr. Kennedy:

The undersigned organizations which represent outpatient radiology practices and imaging centers respectfully request waiving the JW and JZ modifier reporting requirement for Medicare Part B separately payable imaging contrast agents and radiopharmaceuticals in light of the fact that the manufacturers of these products are excluded by law from the mandate to refund CMS for the amount that is unused or discarded. These requirements add a significant amount of additional time, resource, and administrative costs to providers, with no additional benefit to CMS.

Background

Section 90004 of Infrastructure Investment and Jobs Act requires manufacturers to provide a refund to CMS for unused portions of refundable drugs in single-use dose containers or packages.[1] A refundable single-dose container or single-use package drug **does not include a radiopharmaceutical or imaging agent** [emphasis added], certain drugs requiring filtration, and certain new drugs.[2]

In the CY 2023 Medicare physician fee schedule (MPFS) final rule, CMS finalized that for all claims for drugs from single-use vials or single-use packages payable separately under Part B, either the JW modifier would be used to identify any discarded amounts or the JZ modifier would be present to attest that there were no discarded amounts.[3] **This includes drugs excluded from the definition of "refundable single-dose container or single-use package," such as radiopharmaceuticals and contrast agents used in medical imaging**.[4] Drugs drawn from multi-dose containers are exempt from the modifier JW/JZ requirement.[5] Starting July 1, 2023, providers are required to report the JZ modifier on all claims for drugs from single-dose containers that are separately payable under Medicare Part B when there are

[1] Pub. L. 117-9
[2] https://www.govinfo.gov/content/pkg/BILLS-117hr3684enr/pdf/BILLS-117hr3684enr.pdf
[3] https://www.federalregister.gov/d/2022-23873/p-2566
[4] FAQ #7, https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf
[5] Ibid

no discarded amounts. Such claims that do not report the modifiers as appropriate on or after October 1, 2023 may be returned as un-processable.[6]

Therefore, we do not view reporting the amounts of unused imaging contrast agents and radiopharmaceuticals, if any, as providing a benefit to CMS when the agency is prohibited from collecting the corresponding refunds from their manufacturers by statute.

Confusion

The language used in the CY 2023 MPFS final rule and subsequent Frequently Asked Questions (FAQ) is a source of confusion. Many in our industry concluded that the exclusion for radiopharmaceuticals and imaging contrast agents meant that complying with the JW and JZ modifiers was unnecessary. Others were unaware of the requirement because it was not included in the CY 2023 MPFS proposed rule and not explicitly discussed pertaining to outpatient practices or imaging centers in CMS' FAQ, transmittal, or MLN Matters article.[7,8,9]

Unnecessary Administrative Burden

Collecting and documenting imaging contrast agent and radiopharmaceutical use is burdensome. First, there is the shear magnitude of the requirement. We estimate over 3 million imaging studies with contrast agents and over 1.5 million diagnostic nuclear medicine exams involving radiopharmaceuticals are performed annually for Medicare beneficiaries in the office setting.[10]

Second, compliance with the requirement will require updated workflows, revised forms, changes to the radiology information system (RIS). Radiological technologists or other clinical staff will have to record the beginning and ending doses to estimate the amount unused and discarded, if any. This information then will be documented in the radiologist's report; further contributing to "note bloat" of adding administrative information with little to no clinical usefulness to the ordering clinician or the patient. Similarly, radiologist clinical workflows will have to be modified, report templates revised, and RIS updated with the necessary fields. All of this distracts from providing patient care and without any benefit in return. Our experience is not unique, CMS received multiple public comments on the proposed rule regarding the burden associated with implementing this policy. (*We acknowledge and appreciate that CMS did postpone the start-date and claims denial date from January 1, 2023 originally*.)

Finally, radiopharmaceuticals are custom-ordered for the patient and the exam. This is done because they have short radioactive half-lives and to minimize the radiation dose to the patient and risk of prolonged exposure. The specified amount of radiopharmaceutical arrives pre-measured from the manufacturer and ready to be administered to the patient. There is no wastage. Meaning that, each claim for a radiopharmaceutical will be accompanied by the JZ modifier. Thus, applying the JZ modifier to Medicare claims for radiopharmaceuticals is redundant and unnecessary.

Billing and Coordination of Care Challenges

We are concerned that the JZ modifier may result in billing errors, inadvertent claim denials, and slow claims processing, not only for providers but also for CMS. In particular, coordination of care with Medicare supplement plans and Medicare as a secondary payor could be problematic as these payors

[6] Ibid
[7] FAQ
[8] https://www.cms.gov/files/document/r12067cp.pdf
[9] https://www.cms.gov/files/document/mm13056-new-jz-claims-modifier-certain-medicare-part-b-drugs.pdf
[10] Analysis of CMS' 2021 "Medicare Physician & Other Practitioners – by Geography and Service" datafile. https://data.cms.gov/provider-summary-by-type-of-service/medicare-physician-other-practitioners/medicare-physician-other-practitioners-by-geography-and-service

are slower to adopt new modifiers. Clearinghouses used in claims processing will need to update their systems otherwise claims containing the JZ modifier risk being rejected which further delays processing and timely payment to outpatient radiology practices and imaging centers.

Another potential claims issue is the appearance of duplicate billing of the imaging contrast agent or radiopharmaceutical since the same HCPCS code will be reported twice albeit with different modifiers. Importantly, for CMS' claims processing edits, this introduces the potential for error and accidental claims rejection.

Finally, imaging contrast agents come in single-dose and multi-dose containers. As previously stated, drugs in multi-dose containers are exempt from the JW/JZ requirement. Consequently, CMS' claims processing edits will have to distinguish between imaging contrast agents coming from single-use vials versus those from multi-dose containers to ensure correct claims adjudication.

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In summary, the reporting of the JW and JZ modifiers for imaging contrast agents and radiopharmaceuticals by outpatient radiology practices and imaging centers is burdensome and serves no meaningful purpose. We respectively request that this requirement be waived for these drugs. Additionally, while our request is being considered, the July 1st effective date and October 1st claims denial date should be paused.

Thank you in advance for the opportunity to bring this issue to your attention and for considering our request. If you have questions or would like to discuss this further, please contact Michael Mabry, RadNet's Senior Director for Public Policy & Economic Analysis at 443.810.4798 or Michael.Mabry@RadNet.com.

Sincerely,

American College of Radiology
Radiology Business Management Association
RadNet
RAYUS Radiology

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