Attachment A - CMS Response to 60-day Public Comments (CMS-10884)

The Centers for Medicare & Medicaid Services (CMS) received comments from Physicians, American Academy of Ophthalmology (the Academy), American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS), and Outpatient Ophthalmic Surgery Society (OOSS), American Association of Orthopaedic Surgeons (AAOS), AdvaMed, American Medical Association (AMA), American Osteopathic Association (AOA), American Podiatric Medical Association (APMA), State Ambulatory Surgery Center Associations, Ambulatory Surgery Center Association (ASCA), Boston Scientific, Medical Device Manufacturers Association (MDMA), Medical Group Management Association (MGMA), Philips, Regulatory Relief Coalition (RRC), Medical Associations, and Optum Healthcare Company related to CMS-10884. This is the reconciliation of the comments.

1. Comment: CMS received comments about concerns of potential provider and facility burden with implementing the ambulatory surgical center (ASC) prior authorization demonstration.

Proposed Response: CMS believes that this prior authorization demonstration will both help protect the Medicare Trust Fund from improper payments and ensure beneficiaries are not hindered from accessing necessary services when they need them. Prior authorization helps CMS make sure services subject to potential fraud or unnecessary utilization are provided in compliance with applicable Medicare coverage, coding, and payment rules before they are provided. It also allows beneficiaries to know if the service would be covered by Medicare and of any potential financial implications earlier in the process. Burden is reduced by having set timeframes for contractors to complete any prior authorization request decisions, and by establishing an expedited process for cases where delays in the decision could jeopardize the life or health of beneficiaries. In addition, paid claims for which there is an associated affirmed prior authorization decision will be afforded some protection from future audits and possible revocation of payments. Additionally, if a provider is concerned about delaying beneficiary care, the provider is able to provide the service without submitting a prior authorization request, however these will be subject to prepayment review.

2. **Comment:** CMS received comments about concerns of low utilization of some of the codes selected for this prior authorization demonstration. They state that some of the codes have a case volume of zero.

Proposed Response: CMS is conducting this demonstration to combat fraud in the ASC setting. CMS reviewed data on these codes from 2019-2021 which shows these codes being utilized in the ASC setting. However, volume increase isn't the criteria for services being included in this ASC demonstration. CMS selected the services based on reports of fraud occurring within these service categories. While none of the selected codes showed zero utilization according to CMS data, CMS is including several lower volume codes because they are similar to some of the more high-volume codes. Providers may begin to use these codes if they are not included in this demonstration as a means of avoiding the prior authorization process. Placing these codes on the prior authorization list from the outset prevents providers from circumventing the prior authorization process via code shifting later.

3. **Comment:** CMS received a comment asking us to review the data submitted by participating ASCs and consider ending the demonstration early if there is no evidence of fraud, waste and abuse. They also suggest CMS exempt ASCs during years 3-5 of the demonstration if there is no material evidence of fraud, waste, and abuse.

Proposed Response: CMS will review data during the demonstration to determine its effectiveness. CMS will implement an exemption process for those providers who continually show compliance with meeting coverage requirements, and those providers will not need to request prior authorization for all or most of

the selected services. Providers will need to submit at least 10 requests and achieve a prior authorization provisional affirmation threshold of at least 90 percent during an annual assessment. Exempt providers who demonstrate a high claim approval rate, based on an annual spot check review of claims submitted, typically a 10-claim sample, will remain exempt. CMS may withdraw an exemption if evidence becomes available based on a review of claims that such claims do not meet Medicare's billing, coding, or payment guidelines.

4. **Comment:** CMS received comments asking for clarification of the word provider. Specifically, is an "ASC provider" referring to a provider within an ASC, or is it the referring physician? Is the ASC's facility fee, the provider's professional fee, or both are potentially impacted by failure to obtain prior authorization.

Proposed Response: The provider in this context refers to the practitioner rendering one of the targeted services in an ASC. If a claim fails to meet Medicare payment requirements, all fees and costs associated with that claim will be denied, this includes provider fees and facility fees.

5. Comment: CMS received a comment requesting clarifications regarding the expected MAC review process and the applicable turnaround times for these reviews to ensure there is transparency regarding these reviews and the balance with prior authorization is appropriately struck between ensuring quality and safety and reducing unnecessary administrative burdens and delays to patient care.

Proposed Response: CMS will ensure that the MACs have the necessary resources to operate this demonstration. MACs already have a process in place for reviewing prior authorization requests for these services in the OPD setting. CMS also has timeframes set for MACs to ensure that providers are receiving timely decisions to prior authorization requests and beneficiaries do not experience delays in care. Standard prior authorization requests will receive a decision within 7 calendar days. Expedited requests will receive a decision within 2 business days. Originally in the supporting statement, CMS said that expedited requests will receive a decision within 72 hours. In other Medicare Fee-for-Service (FFS) prior authorization programs, expedited requests receive a decision within 2 business days. After evaluation, depending on when the expedited request is submitted, it may take longer for providers to receive a decision using the 72-hour timeframe than the timeframe of 2 business days. Since an expedited review decision timeframe of 72 hours would not reduce beneficiaries' wait time in all circumstances, we will render an expedited decision within 2 business days. If a provider chooses not to request prior authorization, and submits a claim for those services, the services will be subject to prepayment review (meaning that the MAC will make a claim determination before claim payment, using the standard Medicare prepayment review process). For more information on the standard Medicare prepayment medical record review process, please see the CMS Internet-Only Manual, Pub 100-08, Medicare Program Integrity Manual, Chapter 3, §3.2.

6. **Comment:** CMS received a comment concerned about potential delays in approval for medically indicated procedures, directly impacting the timing of care for services delivered to Medicare beneficiaries. They also expressed concerns that while an expedited review decision would be rendered within 2 business days, this extended timeline could nonetheless jeopardize a Medicare beneficiary's life, health, or ability to regain maximum function due to the delay in care. Further, the potential rejection and subsequent appeals process exacerbates the impact on social determinants of health by disproportionately impacting medically underserved patients and the physicians who cannot manage the unpredictability of the process.

Proposed Response: The services selected for the ASC prior authorization demonstration typically do not need to be performed urgently. ASCs are designed for procedures to be scheduled in advance after a

practitioner evaluates the beneficiary. Given the structure of ASCs and that the services selected are not typically performed urgently, we feel that an expedited decision within 2 business days will allow beneficiaries to receive medically necessary care within a reasonable timeframe. Additionally, CMS already has guidelines in place for these services through MAC local coverage determinations, so providers are aware what the requirements are for performing these services. Furthermore, prior authorization is not a condition of payment in this demonstration, and a practitioner may provide a service without submitting a prior authorization request if they believe the wellbeing of their beneficiary would be at risk otherwise, their service would then be subject to prepayment review.

7. **Comment:** CMS received a comment stating that hospital OPDs stand to benefit the most from this demonstration, because patients and referring providers are likely to perceive that they must fulfill additional requirements to obtain care in an ASC setting. The effect could be a "reverse" migration from ASCs to hospital OPDs, when OPDs currently have prior authorizations processes in place for nearly all procedure codes called out in this demonstration.

Proposed Response: Through prior authorization, beneficiaries will have access to medically necessary care that meets Medicare requirements, regardless of the setting the service is performed in. Private insurers are prior authorizing some of these services as well, some examples are BlueCross BlueShield and United Healthcare. With this demonstration, MACs will be utilizing a similar review process for these services as they do in the OPD setting. The documentation requirements that MACs already have for the services in the OPD program can be applied to the ASC services. This demonstration will not create new documentation requirements for these services. The OPD prior authorization program remains in place, so CMS does not anticipate a shift from services being rendered in the ASC back to the OPD setting. CMS will monitor these codes in the ASC and OPD setting for any potential shift.

8. Comment: CMS received a comment asking if the responsibility would shift to the ASC from the physician when the prior authorization request process is not followed, and no prior authorization is obtained? In these instances, additional personnel would need to be hired and the cost would not only be a financial burden on the ASC itself but would lead to an increased cost to Medicare.

Proposed Response: The provider rendering the procedure in the ASC would be responsible for submitting a prior authorization request. When prior authorization is not obtained, the claim will be stopped for prepayment medical review to ensure that medically necessary care was rendered before providing payment. CMS accounted for the additional burden of submitting the request in the PRA package.

9. Comment: CMS received a comment requesting that before expanding prior authorization to other settings of care or services, CMS must confirm that the current OPD prior authorization program is having the desired effect, is not inadvertently limiting access to necessary procedures, and that the associated administrative burden for providers has not led to unintended consequences in patient care.

Proposed Response: Thank you for the feedback. CMS released prior authorization statistics in September 2023 including those for the OPD program. While the MACs are required to review and communicate decisions on prior authorization requests within 10 business days, the average number of days for reviewing standard OPD prior authorization requests was 4.3 days in FY 2021 and 4.5 days in FY 2022. In FY 2021, 79.2% of requests were provisionally affirmed and in FY 2022, 78.8% of requests were provisionally affirmed. These statistics demonstrate that providers are understanding the prior authorization process and are now submitting prior authorization requests only for medically necessary care in the OPD setting. CMS hopes to release more data on the OPD and other prior authorization programs in the future.

10. Comment: CMS received a comment requesting that CMS share the analyses conducted to select the service categories proposed for the ASC prior authorization demonstration program.

Proposed Response: CMS utilizes data from the Integrated Data Repository, a data warehouse of all submitted Medicare claims, to compare trends in utilization and improper payment rates in conjunction with observed cases of fraudulent activity when deciding which services will require prior authorization as a condition of payment. For example, Current Procedural Terminology (CPT) code 15823 (Blepharoplasty, upper eyelid; with excessive skin weighting down lid) saw an 18.9 percent increase in utilization between 2020 and 2021, while CPT code 30520 (Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft) saw an increase of 12.1 percent between 2020 and 2021. There are also cases of fraud surrounding these mostly cosmetic procedures such as United States of America v. Ameet Goyal, 19 Cr. 844 (CS) (S.D.N.Y.)[1] wherein the provider pled guilty to fraudulently billing for blepharoplasty procedures.

11. Comment: CMS received comments concerned about ASCs not having the funding, equipment, staff, or general infrastructure capable of handling prior authorization requests.

Proposed Response: CMS prior authorization programs are designed to minimize provider burden, they require no additional documentation than what should already be maintained when submitting a claim to Medicare for payment, and have review timeframes of 2 business days for expedited requests and 7 calendar days for standard requests. Private insurers have been prior authorizing some of these services as well, such as BlueCross BlueShield and United Health. ASCs typically perform procedures that have been scheduled in advance and are not designed for emergency procedures. In prior authorization, services that receive a provisional affirmation are paid as long as the claim continues to meet Medicare coverage rules. The provisional affirmation allows providers assurance that they will be paid for services before they are rendered. Providers may face more severe financial impacts from having past payments revoked and payment denied for failure to meet conditions of payment, which prior authorization helps to avoid. The provider who is performing the service is responsible for submitting prior authorization or the required documentation for prepay review. No additional documentation is required beyond what is normally required to meet Medicare payment requirements and a provider would be expected to have access to such documentation. Additionally, if a provider is concerned about the burden of submitting a prior authorization request or is concerned about the wellbeing of their beneficiary, they are able to provide the service without prior authorization and undergo prepayment review.

12. Comment: CMS received a comment suggesting that the Medicare Fee-for-Service (FFS) Recovery Audit Program would be more appropriate for investigating fraud.

Proposed Response: The Medicare FFS RACs are responsible for identifying and correcting improper payments through post-payment reviews. Prior authorization is used to prevent improper payments from occurring by ensuring that the services being rendered are medically necessary. Both the Recovery Audit system and Prior Authorization models are important tools for reducing Medicare Fraud and the use of Prior Authorization is appropriate for this demonstration.

13. Comment: CMS received a comment regarding six codes on the prior authorization list (CPT codes 15847[2], 36474[3], 36476[4], 36479[5], 36481[6], and 36483[7]) having a payment indicator N1, meaning they are

[1] https://www.justice.gov/usao-sdny/pr/ophthalmologist-pleads-guilty-seven-year-healthcare-fraud-scheme-and-defrauding-sba

[2] CPT 15847: Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)

not separately payable in the ASC setting so they question including them in a prior authorization demonstration.

Proposed Response: Though these codes have a status indicator of N1 in the ASC payment system, most of the codes listed may be paid separately under the physician fee schedule. By including them in the prior authorization demonstration, CMS will monitor these codes and determine effectiveness of the demonstration. While CPT code 15847 may be packaged and not reimbursed in any setting, it is important to include this code on the prior authorization list to ensure that beneficiaries aren't receiving additional procedures that aren't medically necessary. Please note that CPT code 36481 is not a part of the proposed demonstration.

14. Comment: CMS received a comment citing concerns with prior authorization in Medicare Advantage, noting that Congress has introduced legislation to mitigate the issue, including the Improving Seniors' Timely Access to Care Act, which would make numerous changes reducing prior authorization barriers.

Proposed Response: CMS understands that prior authorization programs with other payers can generate burden and we support efforts to address that burden. This demonstration is already incorporating the burden reducing changes that are included in CMS-0057-F and should benefit ASCs and providers who provide services in that setting by providing greater confidence that they have met Medicare payment requirements before submitting a claim, thus reducing the risk of having past payments rescinded, which can lead to financial harm. The Improving Seniors' Timely Access to Care Act establishes electronic transmission which must comply with certain applicable technical standards as well as other requirements to promote the standardization and streamlining of electronic prior authorization transactions. CMS FFS already has electronic submission of prior authorization requests available for those who want to use it.

15. Comment: CMS received a comment asking this demonstration to use notice and comment rulemaking as part of the OPPS/ASC annual update to solicit additional public input.

Proposed Response: Currently, the ASC demonstration is only for select states. CMS will evaluate the effectiveness of this demonstration before considering any expansion. The goal of prior authorization is to ensure that beneficiaries are receiving medically necessary care while keeping the medical necessity documentation requirements unchanged for providers. There are currently local coverage determinations for the selected services that already give providers guidelines on Medicare coverage and the documentation requirements associated with these procedures. The prior authorization process is not establishing additional requirements for these services. Prior authorization ensures that the requirements for rendering these services are met before the procedure is performed. Also, the services selected for the

[3] CPT 36474: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites

[4] CPT 36476: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites

[5] CPT 36479: Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites

[6] CPT 36481: Percutaneous portal vein catheterization by any method

[7] CPT 36483: Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites

ASC prior authorization demonstration typically do not need to be performed urgently. CMS will continue to seek public input with an additional 30-day comment period.

16. Comment: CMS received a comment stating CMS has not addressed letters from stakeholders and Members of Congress regarding concerns of the OPD program impacting beneficiary access to care.

Proposed Response: CMS has responded to previous concerns from stakeholders received as part of OPD proposed rules comments and all correspondence from Congress regarding the OPD program. We are not aware of any outstanding correspondence to date. CMS collaborated with stakeholder associations and removed several procedure codes from the OPD list of services that require prior authorization as they were likely not cosmetic in nature. CMS' prior authorization programs are designed to minimize provider burden, they require no additional documentation and have review timeframes of just 2 business days for expedited requests and 7 calendar days for standard requests. CMS is not aware that those concerns about the OPD program have materialized and believes the initial years of implementation have been successful.

17. Comment: CMS received a comment asking whether CMS complied with the statutory requirements in Section 402(b). The commenter also inquired about CMS's plans to evaluate the success of the demonstration and questioned whether CMS will be able to devote sufficient resources to the operation and assessment of the demonstration.

Proposed Response: CMS complied with Section 402(b). Specialists within the Department of Health and Human Services who are competent to evaluate the demonstration have provided advice and recommendations. Further, during the course of the demonstration and at its conclusion, CMS will evaluate whether the objectives of the demonstration are being or have been met. CMS will engage with an independent evaluation contractor to determine if there is evidence of reduced fraud, improper payments, and overutilization without decreasing beneficiary access and quality of care.

18. Comment: CMS received a comment urging communication with the MACs regarding the difference between the OPD program and ASC demonstration. They note in the OPD Program claims for services delivered without a provisional affirmation are automatically denied. But in the ASC demonstration claims submitted without a provisional affirmation cannot be summarily rejected and must be reviewed using the standard Medicare prepayment review process. This is necessary to avoid unnecessary appeals and increased burden on providers and Medicare beneficiaries.

Proposed Response: CMS agrees with the differences noted between the OPD prior authorization program being a condition of payment and this being a demonstration where claims are not automatically denied for not having a prior authorization request. All MACs will be directed through specific contractual documents with clear instructions including conducting prepayment review for this ASC prior authorization demonstration.

19. Comment: CMS received a comment requesting evaluation of the role that this demonstration could play in exacerbating disparities in access to care for underserved communities.

Proposed Response: CMS evaluates the health equity impacts of its programs and demonstrations as part of its development and clearance processes and this demonstration is not expected to exacerbate health inequality. CMS will engage with an independent contractor to evaluate this demonstration and determine if there is evidence of reduced fraud, improper payments, and overutilization without decreasing beneficiary access and quality of care. CMS will continue to monitor to verify that this demonstration does not have a disproportionate impact on underserved communities.

20. Comment: CMS received a comment regarding concerns that the proposed demonstration relies on assumptions gathered through the OPD prior authorization program and doesn't account for differences between the sites of service that may increase burden for ASCs. They ask CMS to ensure these reporting requirements minimize burden on ASCs to the greatest extent possible.

Proposed Response: There are no additional documentation requirements, and providers are expected to already have all required documentation to prove medical necessity and compliance with Medicare payment requirements, thus the burden should be limited to compiling information, ensuring completeness and accuracy, and then processing the submission. Both CMS and the MACs will provide outreach and education prior to implementation of this demonstration to ensure understanding of demonstration requirements and operations. MACs will provide ongoing support for providers to make the submission process as quick and accurate as possible.