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The Honorable Seema Verma
Administrator
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** — CY 2021 OPPS/ASC Proposed Rule — ASC Separate Payment for OMIDRIA (J1097)

Dear Administrator Verma:

As legal counsel to Omeros Corporation ("Omeros"), we appreciate the opportunity to comment on the CY 2021 Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (Proposed Rule).[1] In specific, this letter articulates the legal basis for separate payment of Omeros's non-opioid pain management surgical drug for postoperative pain OMIDRIA® (phenylephrine and ketorolac intraocular solution 1%/0.3%) when administered in the Ambulatory Surgical Center (ASC) setting.

In a separate comment letter, Omeros provides detailed substantive comments in support of CMS's proposal to continue the same payment methodologies for policy-packaged non-opioid pain management surgical drugs as it did in CY 2019 and CY 2020. In that letter, Omeros also requests that CMS apply that policy to OMIDRIA in the CY 2021 Final Rule, in the same manner as CMS currently applies that policy to the non-opioid pain management surgical drug EXPAREL®.

The purpose of this supporting legal comment letter is twofold. First, this letter summarizes the legal and regulatory basis for the separate payment of OMIDRIA under the existing non-opioid pain management ASC drug policy, established by CMS in the CY 2019 Final Rule and which the Proposed Rule proposes to continue unchanged for CY 2021. Second, this letter summarizes the well-established case law on the logical outgrowth doctrine, which

[1] 85 Fed. Reg. 48772 (Aug. 12, 2020).

precludes alterations to the existing non-opioid pain management surgical drug policy between the CY 2021 Proposed Rule and the CY 2021 Final Rule.

Under the existing CY 2019 policy, OMIDRIA is eligible for separate payment in the ASC starting October 1, 2020 when it comes off pass-through and is policy packaged. However, it is critical to emphasize that although OMIDRIA has been mentioned by CMS in previous rulemakings, *CY 2021 is the first full calendar year in which OMIDRIA will be policy packaged rather than on pass-through, and thus the first full year that the drug is eligible for payment under the CY 2019 policy*. The CY 2021 rulemaking is therefore the first opportunity for CMS to state in rulemaking that its 2019 policy also applies to OMIDRIA. We are currently addressing with HHS the process needed to receive a K2 designation for separate payment in the ASC setting for OMIDRIA for the fourth quarter of 2020.

I. BACKGROUND ON OMIDRIA

OMIDRIA, manufactured by Omeros, is a U.S. Food and Drug Administration (FDA)-approved drug indicated for use during cataract surgery or intraocular lens (IOL) replacement. It is added to an ocular irrigating solution and is indicated for maintaining pupil size by preventing intraoperative miosis (pupil constriction) and *for reducing postoperative pain*.[2] The FDA label shows that it is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor. Its pharmaceutical ingredients are phenylephrine and ketorolac.[3] OMIDRIA *does not* contain an opioid.

OMIDRIA is currently paid separately in the HOPPS and ASC setting through the transitional pass-through program under HCPCS code J1097. OMIDRIA's pass-through status expires as of September 30, 2020 as required by section 1833(t)(6)(G) of the Social Security Act, as added by section 1301(a)(1)(C) of the Consolidated Appropriations Act of 2018.[4] CMS considers OMIDRIA to be a drug that functions as a supply in a surgical procedure and has stated its intention in the CY 2021 HOPPS/ASC proposed rule to package OMIDRIA in the OPPS and ASC setting when the drug's pass-through status expires on September 30, 2020.

[2] OMIDRIA's FDA-approved label is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.
[3] *Id.*
[4] Consolidated Appropriations Act of 2018, Pub. L. No. 115-141 (Mar. 23, 2018).

II. THE EXISTING CMS LEGAL FRAMEWORK REQUIRES SEPARATE PAYMENT OF OMIDRIA — A NON-OPIOID POSTSURGICAL PAIN MANAGEMENT DRUG — IN THE ASC SETTING

A. CMS established five objective regulatory criteria for separate payment of non-opioid pain management drugs that function as a supply in a surgical procedure

In the CY 2019 OPPS/ASC rulemaking, CMS finalized a policy to "unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2019…."[5] In doing so, CMS articulated a straightforward, objective five-part test for when CMS will unpackage and pay separately for the costs of non-opioid pain management drugs that function as a supply in a surgical procedure. To qualify, drugs used in the ASC setting must be: (1) FDA-approved, (2) pain management drug, (3) non-opioid, (4) considered by CMS to function as a supply in a surgical procedure, and (5) otherwise policy packaged.

The CY 2021 OPPS/ASC Proposed Rule proposes continuing this policy in CY 2021, to pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting. Separately, the CY 2021 Proposed Rule would continue to package payment for non-opioid pain management drugs that function as surgical supplies in the hospital outpatient department setting.[6] This legal memorandum focuses solely on payment for OMIDRIA in the ASC setting.

Under this ASC policy, CMS determined in both CY 2019 and 2020, under the five-factor test outlined above, that the drug EXPAREL® qualifies for separate payment because it is "*currently* the only [non-opioid pain management] drug used in the ASC setting that is both covered under Medicare Part B and policy packaged as a drug that functions as a supply in a surgical procedure."[7] However, CMS made clear that the ASC separate payment policy for non-opioid postsurgical pain management drugs would extend to *any* qualifying drugs in the future, stating that "[t]o the extent that other non-opioid pain management drugs become available on the U.S. market in 2019, *this policy would also apply to those drugs*" (emphasis supplied).[8]

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[5] 83 Fed. Reg. 58818, 59071 (Nov. 21, 2018).
[6] 85 Fed. Reg. at 48979.
[7] 83 Fed. Reg. at 59068, *supra* n. 4 (emphasis added); 84 Fed. Reg. 61142, 61180 (Nov. 12, 2019).
[8] 83 Fed. Reg. at 58858.

B. OMIDRIA meets all five regulatory criteria for separate payment in the ASC setting.

In the CY 2019 OPPS/ASC Final Rule, CMS stated expressly that its ASC policy to pay separately for non-opioid pain management drugs applied prospectively.[9] OMIDRIA meets all five objective regulatory requirements, established by CMS through rulemaking, for separate payment in the ASC setting.

1. OMIDRIA is FDA-approved for intraocular use in cataract procedures.[10]

2. OMIDRIA is a pain management drug. Its FDA label states that it is "indicated for: Maintaining pupil size by preventing intraoperative miosis [and] reducing postoperative pain."[11] CMS confirmed this in the CY 2020 OPPS/ASC final rule: "Omidria is indicated for maintaining pupil size by preventing intraoperative miosis and reducing postoperative ocular pain in cataract or intraocular surgeries."[12]

3. OMIDRIA does not contain an opioid. The FDA label for OMIDRIA shows that it is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor.[13] Its pharmaceutical ingredients are phenylephrine and ketorolac.[14] CMS has also already acknowledged that OMIDRIA contains no opioids.[15]

4. OMIDRIA functions as a surgical supply during cataract surgery. CMS has repeatedly ruled that "[w]e consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy."[16]

5. Upon expiration of pass-through status, OMIDRIA will be packaged "per OPPS policy" (and will therefore qualify to be paid separately under the ASC payment system for its use in ASC settings) when its existing pass-through status expires.[17]

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[9] 83 Fed. Reg. at 59068 ("To the extent that other non-opioid drugs that function as surgical supplies come onto the U.S. market, we proposed that this policy would apply to them as well in CY 2019"). As CMS acknowledged in the CY 2019 OPPS/ASC Final Rule, there was only one product on the market at that time — EXPAREL® — that qualified for CMS' newly promulgated policy regarding non-opioid pain management drugs, since OMIDRIA was on pass-through status at the time. As with OMIDRIA, EXPAREL® had previously been on pass-through status prior to qualifying for separate payment under this policy. *See* 83 Fed. Reg. at 58855 ("Exparel had pass-through payment status from CYs 2012 through 2014 and was separately paid under both the OPPS and the ASC payment system during this 3-year period.").

[10] OMIDRIA, *supra* n.1.

[11] *Id.*

[12] 84 Fed. Reg. at 61178, 61179, and 61402.

[13] OMIDRIA, *supra* n. 1.

[14] *Id.*

[15] See CMS study discussed at 84 Fed. Reg. at 61179 and 61402 (comparing cataract procedures on Medicare patients where OMIDRIA was not used to cataract procedures on Medicare patients where OMIDRIA was used to determine the extent to which OMIDRIA contributed to a decrease in opioid usage).

[16] 79 Fed. Reg. 66875; 82 Fed. Reg. 59216, 59344 (Dec. 14, 2017)

[17] 84 Fed. Reg. at 61310, 61311, & Table 42.

CMS has said that OMIDRIA will be packaged under the OPPS when its current pass-through status ends on or after September 30, 2020.[18] CMS has also stated that OMIDRIA will be policy-packaged in CY 2021.[19]

III. CMS HAS NOT ESTABLISHED IN RULEMAKING ANY *ADDITIONAL* PRODUCT-SPECIFIC EVIDENTIARY REQUIREMENTS – OR ANY OTHER ADDITIONAL CRITERION – THAT A NON-OPIOID ALTERNATIVE MUST MEET TO QUALIFY FOR SEPARATE ASC PAYMENT

In the CY 2019 and 2020 OPPS/ASC Final Rules, CMS reviewed clinical evidence and claims data for several non-opioid drugs within the framework of existing packaging categories, but never adopted (nor proposed to adopt) a policy that requires the use of clinical evidence or claims data for determining whether a specific drug qualifies under the policy.

With respect to clinical evidence, CMS invited the public to submit peer-reviewed evidence during the CY 2019 rulemaking process to show that non-opioid pain treatments reduce opioid use, but for the specific purpose of "to determine whether to adopt a final *policy*."[20] CMS said "*any evidence* demonstrating the reduction or avoidance of prescription opioids would be the criterion we use" to determine if a change to its payment system was warranted and, that if this evidence changes over time, CMS would consider whether a reexamination of any "*policy adopted*" would be necessary (emphases supplied).[21] CMS has made no changes to its policy for non-opioid pain management surgical drugs since it was first adopted. It was extended without change in CY 2020, and the proposal for CY 2021 is to extend it once again without change.

With respect to claims data, CMS referenced EXPAREL®'s claims data during the broader discussion of whether CMS should depart from its long-established payment policy of packaging non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when furnished in the ASC setting.[22] However, it is clear from that discussion that CMS's analysis focused on EXPAREL® because EXPAREL® was the *only* packaged non-opioid pain management drug at the time (as OMIDRIA had pass-through status and was not packaged during that time frame). In responding to Omeros's comment letter on the CY 2019 Proposed Rule (requesting that "CMS explicitly state that

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[18] *Id.*

[19] 85 Fed. Reg. at 48868 (see discussion for HCPCS code J1097 (Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml) and corresponding OPPS listing in Addendum B).

[20] 83 Fed. Reg. 37167 (emphasis added).

[21] 83 Fed. Reg. 58857 ("We also requested comments that provide evidence (such as published peer-reviewed literature) we could use to determine whether these products help to deter or avoid prescription opioid use and addiction as well as evidence that the current packaged payment for such non-opioid alternatives presents a barrier to access to care and, therefore, warrants separate payment under either or both the OPPS and the ASC payment system. We stated that any evidence demonstrating the reduction or avoidance of prescription opioids would be the criterion we use to determine whether separate payment is warranted for CY 2019. We also stated that if evidence changes over time, we would consider whether a reexamination of any policy adopted in the final rule would be necessary.").

[22] 83 Fed. Reg. at 59066-68; 84 Fed. Reg. at 61402.

[OMIDRIA] will also be paid for separately in the ASC setting after pass-through payment status ends for the drug in 2020,")[23] CMS noted that while the policy "is applicable to non-opioid pain management drugs that are currently packaged under the policy for drugs that function as a surgical supply when used in the ASC setting, *which currently is only Exparel,*" CMS confirmed that "[t]o the extent that other non-opioid pain management drugs become available on the U.S. market in 2019, *this policy would also apply to those drugs*." (Emphases supplied).[24]

Moreover, while CMS did reference EXPAREL® claims data in its CY 2020 Final Rule,[25] CMS did so only as a means of determining whether CMS should continue its broader policy for separate payment under the ASC payment system. Nothing in the Rule indicates that CMS relied on claims data as an *additional* criterion for determining whether any *individual* drug, including EXPAREL®, qualifies under the ASC payment system. This conclusion is amply supported by the fact that CMS never proposed or adopted in either the CY 2019 or 2020 rules (or implementing regulations) any "evidence requirement" beyond the five-part test discussed above for non-opioid pain management drugs that function as surgical supplies to be paid separately in the ASC setting. Indeed, in the CY 2021 Proposed Rule, CMS states that it did not believe that additional evidence would warrant CMS altering that policy:

> We are committed to evaluating our current policies to adjust payment methodologies, if necessary, in order to ensure appropriate access for beneficiaries amid the current opioid epidemic. *However, we do not believe conducting a similar CY 2021 review [of claims data] would yield significantly different outcomes or new evidence that would prompt us to change our payment policies under the OPPS or ASC payment system*.[26]

(Emphasis supplied).

IV. ALTERING THE EXISTING POLICY IN THE CY 2021 FINAL RULE WOULD NOT CONSTITUTE A "LOGICAL OUTGROWTH" AND IS PRECLUDED BY LAW

Because the CY 2019 policy does not contain any evidentiary requirement for separate payment for non-opioid postsurgical pain management drugs, as a matter of settled law CMS may not now impose such a requirement absent notice-and-comment rulemaking. In *Azar v. Allina Health Services*, the Supreme Court was unambiguous: CMS must provide notice and the opportunity to comment for any requirement that "changes a substantive legal standard governing . . . the payment for services."[27]

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[23] 83 Fed. Reg. at 58857.
[24] 83 Fed. Reg. at 58857, 58858.
[25] 84 Fed. Reg. at 61402.
[26] 85 Fed. Reg. at 48797.
[27] 139 S. Ct. 1804 (2019).

Although an agency has certain discretion to modify proposed rules in response to comments it receives,[28] its discretion is circumscribed: any change in a final rule must be the "logical outgrowth" of the proposed rule.[29] "A rule is deemed a logical outgrowth if interested parties 'should have anticipated' that the change was possible and thus reasonably should have filed their comments on the subject during the notice-and-comment period."[30] Courts have held repeatedly that a final rule was *not* a logical outgrowth of a proposed rule in "situations where the proposed rule gave no indication that the agency was considering a different approach, and the final rule revealed that the agency had completely changed its position."[31]

Here, CMS did not solicit comments in the CY 2021 Proposed Rule on alternative policies for the separate payment of non-opioid pain management drugs. Nor did CMS provide in the Proposed Rule any "indication that the agency was considering a different approach" to revise or supplement the objective standard established in the CY 2019 Final Rule and continued without change in the CY 2020 Final Rule (for instance, by proposing to add a new clinical evidence-based prong to that test). To the contrary, CMS plainly indicated that it intended to continue its non-opioid pain management drug payment policy *without change*.[32] Consequently, as a matter of law, the CY 2021 Final Rule is constrained to adhere to the requirements that were properly established through notice and comment rulemaking in the CY 2019 final rule.[33]

Put differently, any new evidence-based requirement imposed in the CY2021 Final Rule would not be a logical outgrowth of the CY 2021 Proposed Rule, and would by any measure constitute a "change [in] a substantive legal standard governing . . . the payment for services." Accordingly, CMS is not permitted under controlling precedent to establish in the CY 2021 Final Rule a new clinical evidence requirement to determine whether an individual non-opioid postsurgical pain management drug qualifies for separate payment policy in the ASC setting.

V. CONCLUSION

For the reasons discussed above, OMIDRIA qualifies for separate payment as a non-opioid pain management drug used as a surgical supply in the ASC setting under the objective

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[28] *Northeast Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004) (per curiam).

[29] Social Security Act § 1871(a)(4). *See also Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007); *National Black Media Coalition v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986) ("While a final rule need not be an exact replica of the rule proposed in the Notice, the final rule must be a 'logical outgrowth' of the rule proposed.").

[30] *Northeast Md. Waste Disposal Auth.*, 358 F.3d at 952.

[31] *CSX Trans. Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1082 (D.C. Cir. 2009).

[32] 85 Fed. Reg. at 48797. ("Therefore, for CY 2021, we propose to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021.).

[33] This is in contrast to a situation in which an agency affirmatively indicates in a proposed rule that they are considering taking policy action to address an issue of concern, *see City of Portland v. EPA*, 507 F.3d 706, 715 (D.C. Cir. 2007).

standard established in the CY 2019 OPPS/ASC Final Rule. Furthermore, where CMS has affirmatively proposed no changes to that policy in the CY 2021 Proposed Rule, CMS may not utilize the CY 2021 Final Rule to establish additional requirements for separate payment under that policy.

Should you have any questions regarding the above comment or analysis, or if I can provide any clarification that will assist the agency, please do not hesitate to contact me directly.

Sincerely,

Thomas R. Barker