September 25, 2020

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:

On behalf of 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 (CY 2021 Proposed Rule).[1] Omeros is a Seattle-based biopharmaceutical company that has developed and commercialized OMIDRIA® (phenylephrine and ketorolac intraocular solution 1%/0.3%), the only drug of its kind for cataract surgery, and is advancing small-molecule and protein therapeutics against wholly novel drug targets focused on complement-mediated diseases, immuno-oncology, and disorders of the central nervous system. This comment letter is directed to OMIDRIA, a non-opioid pain management drug approved by the U.S. Food and Drug Administration (FDA) and used during surgery with an FDA-approved label indication to reduce postoperative pain. Throughout CY 2021, OMIDRIA will be policy-packaged by CMS.[2] This is because CMS considers it to be a surgical supply in the performance of surgical procedures.[3]

In the CY 2021 Proposed Rule, CMS has articulated a very clear proposal for policy-packaged non-opioid pain management surgical drugs. Specifically, CMS has said: "***we propose to continue our policy to unpackage and pay separately at ASP+6 percent for the cost of nonopioid 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 nonopioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021***."[4] CMS first

[1] 85 Fed. Reg. 48772 (Aug. 12, 2020).
[2] 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).
[3] 82 Fed. Reg. 59216, 59345 (Dec. 14, 2017) (CMS said, "[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."
[4] *Id.* at 48979.

The Omeros Building
201 Elliott Avenue West
Seattle WA, 98119

p 206.676.5000
f 206.676.5005

www.omeros.com

codified its policy to unpackage and pay separately for non-opioid pain management surgical drugs when used in ASC settings in the CY 2019 OPPS/ASC final rule[5] and has continued the policy without change in subsequent years. Throughout CY 2021, CMS proposes to continue to use the same payment methodologies for policy-packaged non-opioid pain management surgical drugs as it did in CY 2019 and CY 2020, without change.

While CMS does not pay separately for policy-packaged non-opioid pain management surgical drugs when used in the OPPS, it does pay separately for them when used in the ASC setting. In the CY 2019 OPPS/ASC final rule, CMS concluded that "we have not found evidence to support the notion that the **OPPS** packaging policy has had an unintended consequence of discouraging the use of non-opioid treatment for postsurgical pain management in the hospital outpatient department."[6] In contrast, CMS concluded that "fluctuations in payment rates for specific services may impact [ASC] providers more acutely than hospital outpatient departments, and therefore **ASCs** may be less likely to choose to furnish non-opioid postsurgical pain management treatments, which are typically more expensive than opioids, as a result."[7] In the CY 2020 OPPS/ASC final rule, CMS again found no evidence to support a change to its OPPS payment system and maintained the same bifurcated payment methodology for policy-packaged non-opioid pain management surgical drugs in CY 2020 as it did in CY 2019.[8]

CMS proposes to continue to use the same payment methodologies throughout CY 2021 for policy-packaged non-opioid pain management surgical drugs as it did in CY 2019 and CY 2020, without change. We strongly support CMS' proposal to continue its payment policy to unpackage and pay separately for policy-packaged non-opioid pain management surgical drugs when used in the ASC in CY 2021.

Although CMS does not require provision of claims or clinical data in order to qualify in the ASC setting as a non-opioid pain management surgical drug (CMS used this type of evidence to support *establishing* its policy, not to establish product-specific eligibility requirements),[9] we have provided additional clinical background on OMIDRIA demonstrating that its use reduces opioids to further support CMS in adopting its CY 2021 proposed policy. As explained in detail below, upon the expiration of its current pass-through status on October 1, 2020, OMIDRIA will be

[5] 83 Fed. Reg. 58818, 59071 and 59072 (Nov. 21, 2018).
[6] *Id.* at 58855 and 59067 (emphasis added).
[7] *Id.* at 58856 and 59067 (emphasis added).
[8] 84 Fed. Reg. 61142, 61176 (Nov. 12, 2019) ("The results of our review and evaluation of our claims data do not provide evidence to indicate that the OPPS packaging policy has had the unintended consequence of discouraging the use of non-opioid treatments for postsurgical pain management in the hospital outpatient department. Therefore, based on this data evaluation, we stated in the proposed rule that we do not believe that changes are necessary under the OPPS for the packaged drug policy for drugs that function as a surgical supply, nerve blocks, surgical injections, and neuromodulation products when used in a surgical procedure in the OPPS setting at this time.").
[9] While CMS invited the public during the CY 2019 rulemaking process to submit peer-reviewed evidence to show that non-opioid pain treatments reduce opioid use, it did so stating that it would use the evidence "to determine whether to adopt a final *policy*." 83 Fed. Reg. 37167.

policy-packaged and will qualify for separate payment under the ASC payment system, which clearly states that non-opioid pain management drugs that function as supplies in a surgical procedure are to be unpackaged and paid separately when used in the ASC setting.

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.

Separately, we have attached a letter from our legal counsel summarizing the legal standard for separate payment in the ASC setting as a non-opioid pain management surgical drug. **We request that CMS assign a corresponding ASC payment indicator of "K2" to HCPCS J1097 and pay for OMIDRIA at ASP +6 when it is used in the ASC setting.**

I. BACKGROUND ON OMIDRIA

OMIDRIA is approved by FDA as a drug 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*.[10] The FDA-approved label shows that it is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor. Its pharmaceutical ingredients are phenylephrine and ketorolac.[11] OMIDRIA *does not* contain an opioid.

OMIDRIA was a revolutionary development for patients undergoing cataract surgery. Prior to the availability of OMIDRIA, cataract surgeons only had available less effective and/or more complex and dangerous methods to maintain pupil size during surgery. To manage surgical pain, cataract surgery patients often receive fentanyl – an addictive opioid – during surgery, and some surgeons prescribe opioids for postoperative pain management. Now, with the advent of OMIDRIA, cataract surgeons can safely and effectively prevent pupil constriction during surgery, reduce the need for pupil-expansion devices, and prevent both intraoperative floppy iris syndrome (IFIS) and complications including sight-threatening cystoid macular edema. Recent studies detailed in manuscripts already published or submitted for publication in peer-reviewed medical journals also demonstrate that OMIDRIA

[10] OMIDRIA's FDA-approved label is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.
[11] *Id.*

reduces the need for the opioid fentanyl during surgery and reduces prescriptions for opioids post-surgery.[12]

OMIDRIA is administered during a surgical procedure in either the HOPPS or ASC setting, and the drug is currently paid separately 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.[13] CMS considers OMIDRIA to be a drug that functions as a supply in a surgical procedure and has proposed in the CY 2021 Proposed Rule to policy-package OMIDRIA when the drug's pass-through status expires on September 30, 2020.[14]

II. CMS Established Separate Payment of Non-Opioid Pain Management Drugs that Function as a Supply in a Surgical Procedure in the ASC Setting.

In the CY OPPS/ASC 2019 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…."[15]** CMS proposed this policy in response to a November 2017 recommendation by the President's Commission on Combating Drug Addiction and Opioid Crisis for CMS to "examine payment policies for non-opioid pain management drugs that function as a surgical supply, with the overall goal of combating the current opioid addiction crisis."[16]

CMS codified this separate payment policy in regulations by excluding from the definition of a "facility service" an exception for non-opioid pain management drugs that function as a supply when used in a surgical procedure.[17] CMS further codified this separate payment policy with a corresponding objective addition to the definition of a "covered ancillary service," to provide that "[n]on-opioid pain management drugs that function as a supply when used in a surgical procedure" are eligible for separate payment.[18]

Importantly, and in contrast to other types of limitations that CMS has previously imposed within classifications, the regulations do not qualify "non-opioid pain

[12] *Id.*
[13] Consolidated Appropriations Act of 2018, Pub. L. No. 115-141 (Mar. 23, 2018).
[14] 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 listing in Addendum B).
[15] 83 Fed. Reg. at 59071 (Nov. 21, 2018) (emphasis added).
[16] *Id.* at 59068; *see* Recommendation 19 of Commission's Report (emphasis added), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf.
[17] 42 CFR § 416.164(a)(4).
[18] 42 C.F.R. § 416.164(b)(6); *See also* 42 C.F.R. § 416.171(b)(1) (adopting a conforming change to exclude non-opioid pain management drugs that function as a supply when used in a surgical procedure from its policy to pay for ASC covered ancillary services an amount derived from the payment rate for the equivalent item or service under the OPPS).

management drugs" with the term "certain,"[19] which indicates that CMS intended for all non-opioid pain management drugs that meet the enumerated objective criteria (see below) to be separately paid. Finally, the regulations specifically exclude non-opioid postsurgical pain management drugs that function as a supply when used in a surgical procedure from CMS' policy, for ASC covered ancillary services, to pay an amount derived from the payment rate for the equivalent item or service under the OPPS.[20]

Under this ASC policy, CMS determined in both CY 2019 and 2020 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."[21] 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).[22]

III. OMEROS SUPPORTS THE PROPOSED CONTINUATION OF THE ASC SEPARATE PAYMENT POLICY FOR NON-OPIOID PAIN MANAGEMENT DRUGS

Omeros supports the CY 2021 Proposed Rule's continuation of its 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…."[23] As discussed in the CY 2021 Proposed Rule, CMS has not amended its regulations since the CY 2019 OPPS/ASC rulemaking.[24]

We support CMS' current regulatory criteria for separate payment of non-opioid pain management drugs furnished in the ASC setting. Notably, the existing policy does not contain product-specific evidentiary requirements. Moreover, CMS never proposed to include any.

When CMS invited the public during the CY 2019 proposed rulemaking process to submit peer-reviewed evidence to show that non-opioid pain treatments reduce opioid use, the agency stated that it would use the evidence "to determine whether to adopt a final *policy*."[25] CMS said "*any evidence* demonstrating the reduction or avoidance of prescription opioids would be the criterion we use" to determine if there is evidence to warrant a change to its payment system and, that if this evidence changes over

[19] *See* 42 C.F.R. § 416.164(b)(2) ("certain implantable items…."); § 416.164(b)(4) ("certain drugs and biologicals…."); § 416.164(b)(5) ("certain radiology services and certain diagnostic tests….").
[20] 42 C.F.R. § 416.171(b)(1).
[21] 83 Fed. Reg. at 59068, *supra* n. 4 (emphasis added); 84 Fed. Reg. 61142, 61180 (Nov. 12, 2019).
[22] 83 Fed. Reg. at 58858.
[23] 85 Fed. Reg. at 48979.
[24] *Id.* at 4878-79.
[25] 83 Fed. Reg. 37167 (emphasis added).

time, it would consider whether a reexamination of any "*policy adopted"* would be necessary. (emphases supplied).[26]

CMS similarly reviewed clinical evidence and claims data for several non-opioid drugs in response to comments received during the 2020 OPPS/ASC rulemaking process—but while CMS reviewed these data as part of its policy deliberations for the OPPS writ large, the Agency neither proposed nor adopted in regulations any standard requiring a change to its adopted policy for non-opioid pain management drugs that function as surgical supplies in the ASC setting.[27]

Indeed, CMS affirmatively acknowledges in the CY 2021 Proposed Rule that causally attributing changes in utilization to Medicare packaging payment policy alone is difficult to establish. CMS also further concludes that eliminating potential Medicare payment disincentives to prescribe non-opioids is best accomplished not through a subjective analysis of whether a given non-opioid pain management drug's efficacy at reducing the use of prescription opioids can be ascertained from claims data analysis, but instead through an objective separate payment policy for non-opioid pain management drugs:

> Our updated review of claims data showed a continued decline in the utilization of Exparel in the ASC setting, which supported our proposal to continue paying separately for Exparel in the ASC setting. Decreased utilization could potentially indicate that the packaging policy is discouraging use of that treatment and that providers are choosing less expensive treatments. *However, it is difficult to attribute causality of changes in utilization to Medicare packaging payment policy only. We believe that unpackaging and paying separately for Exparel addresses decreased utilization because it eliminates any potential Medicare*

[26] 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.").

[27] Nor did CMS rely upon or reference Section 6082 of the SUPPORT Act as legal authority for its separate payment policy, even though the CY 2019 OPPS/ASC final rule was finalized *after* enactment of the SUPPORT Act. Instead, CMS stated that its separate payment policy was "responsive to the Commission's recommendation": to "review and modify ratesetting policies that discourage the use of non-opioid treatments for pain, such as certain bundled payments that make alternative treatment options cost prohibitive for hospitals and doctors, particularly those options for treating immediate postsurgical pain…." 83 Fed. Reg. at 58857, 58854 (quoting the Commission's Report at page 57, Recommendation 19). Indeed, the only mention of Section 6082 was a generic statement that CMS would "continue to analyze…access to non-opioid alternatives in the OPPS and ASC settings as [the agency] implements section 6082…." 83 Fed. Reg. at 59072.

> *payment disincentive for the use of this non-opioid alternative, rather than prescription opioids.*[28] (Emphasis supplied).

With this clarification from CMS, it is clear that whether a given non-opioid pain management drug is packaged depends *not* on a subjective determination of whether claims data suggests utilization is or is not sufficient but, instead, on whether a given non-opioid pain management drug meets the objective standard for separate payment when used in the ASC setting.

IV. OMIDRIA MEETS ALL FIVE REGULATORY CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING AS A NON-OPIOID PAIN MANAGEMENT DRUG

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. 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.

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**.[29]

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."[30] 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."[31]

3. **OMIDRIA is a non-opioid in that its chemical structure does not contain an opioid.** The FDA label for OMIDRIA shows that it is an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor.[32] Its pharmaceutical ingredients are phenylephrine and ketorolac.[33] CMS has also

[28] 85 Fed. Reg. at 48797.
[29] OMIDRIA, *supra* n.10.
[30] *Id.*
[31] 84 Fed. Reg. at 61178, 61179, and 61402.
[32] OMIDRIA, *supra* n. 10.
[33] *Id.*

already correctly acknowledged that OMIDRIA contains no opioids.[34]

4. **OMIDRIA functions as a surgical supply during cataract surgery.** CMS has said, "[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."[35]

5. **Upon expiration of pass-through status, OMIDRIA will be packaged "per OPPS policy" as a surgical supply**.[36] CMS has said that OMIDRIA will be packaged under the OPPS when its current pass-through status ends on or after September 30, 2020.[37] CMS also indicates in the proposed rule that OMIDRIA will be policy-packaged for CY 2021.[38]

As explained in the attached legal comment letter, CMS' established regulatory criteria for the separate payment of non-opioid pain management drugs does not include an evidentiary standard.

V. OMIDRIA REDUCES DEPENDENCE ON OPIOIDS FOR PATIENTS WHO REQUIRE CATARACT SURGERY

While CMS did not establish in rulemaking product-specific evidentiary requirements that a non-opioid alternative must meet to qualify for separate ASC payment, there is extensive clinical evidence and literature that OMIDRIA *does* reduce dependence on opioids for patients who require cataract surgery. Pain control is critically important for patients undergoing cataract surgery. Up to 35 percent of cataract surgery patients experience moderate-to-severe pain postoperatively.[39] Studies have shown that physicians may use opioids, including fentanyl,[40] for pain both during surgery[41] and to manage postoperative pain.[42] Intraoperatively, many cataract surgery practices use

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[34] 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).

[35] 82 Fed. Reg. at 59345.

[36] 84 Fed. Reg. at 61310, 61311, & Table 42.

[37] *Id.*

[38] 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).

[39] Porela-Tiihonen S, Kaarniranta K, Kokki H. *Postoperative pain after cataract surgery*. J CATARACT REFRACT SURG. 2013;39(5):789-98

[40] Rosero EB. *Monitored anesthesia care in adults*. Joshi GP, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com.

[41] Yalcin Cok O, *et al*. *Comparison of midazolam sedation with or without fentanyl in cataract surgery.* ACTA ANAESTH. BELG. 2008; 59: 27-3; Aydin ON, Kir E, Ozkan SB, Gursoy F. *Patient-controlled analgesia and sedation with fentanyl in phacoemulsification under topical anesthesia*. J CATARACT REFRACT SURG. 2002;28(11):1968-72.

[42] Alam A, Gomes T, Bell CM. *Long-term Analgesic Use: Sometimes Less Is Not More-Reply*. ARCH INTERN MED. 2012;172(15):1189-90.

fentanyl as part of their routine protocol for monitored anesthesia care. In a retrospective assessment at a premier university teaching hospital for ophthalmic surgery, greater than 95 percent of cataract surgery cases included fentanyl as a central component of anesthesia. Published literature also reports that approximately 5 percent of cataract surgery patients, or in excess of 20,000 patients annually, were prescribed an opioid postoperatively and, of all of the low-risk surgical procedures examined, cataract surgery had the largest odds ratio for risk of long-term opioid use. In fact, cataract surgery patients who receive opioids postoperatively have a 60 percent increased risk of using opioids long-term.[43]

In a published peer-reviewed prospective and masked comparative study conducted by Donnenfeld et al., OMIDRIA administered intracamerally during cataract surgery was compared to intracamerally delivered epinephrine, and patients were assessed for need for opioids (specifically fentanyl) and for pain. The study found that use of intraoperative OMIDRIA reduced the need for fentanyl during cataract surgery by nearly 80 percent while concurrently decreasing pain scores by more than 50 percent.[44] David Clark M.D Ph.D., an international expert on pain management and opioid use disorder, confirmed the importance of the Donnenfeld data with respect to the cataract surgery population and opioid-dependent population. By decreasing the total opioid exposure resulting from an elderly patient's collective medical care encounters, use of OMIDRIA limits the risk of opioid use disorder, imparting a better safety profile for the patient and the community.[45]

Another recent study details the data from an IBM Watson analysis of approximately 220,000 cataract surgery-related claims for procedures performed over a 45-month period in Medicare and Medicare-aged patients without recent opioid use. The retrospective study compared adults over 65 without recent opioid use in the MarketScan databases who had a cataract-related surgical procedure between January 1, 2015 and July 31, 2019. Opioid prescribing patterns in the initial 2 and 7 days following surgery were compared between patients who did or did not receive OMIDRIA during surgery. Within 2 days of surgery, 0.50% of OMIDRIA-treated patients and 0.68% of those not receiving OMIDRIA received at least 1 opioid prescription (p=0.129). Pill counts in the first prescription post-surgery were lower for patients who received OMIDRIA than those who did not receive OMIDRIA (20 vs. 45 respectively, p=0.015). Findings were similar when a 7-day window was used. The reduction in opioids prescribed to patients who received OMIDRIA occurred despite the OMIDRIA-treated patients having a significantly higher incidence of preoperative comorbidities or risk factors for surgical complexity than patients who did not receive OMIDRIA (46.6% vs 31.3%, p<0.001). A manuscript detailing these data is currently in the review process at a peer-reviewed publication.

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[43] *Id.*; *see also* Kolomeyer, A; Yu, Y; VanderBeek, B. *Association of Opioids With Incisional Ocular Surgery.* JAMA OPHTHALMOL. Published online Sept. 19, 2019.
[44] Donnenfeld ED, et al. *The effect of OMIDRIA® (phenylephrine and ketorolac intracameral solution 1%/0.3%) on pain and opioid usage during cataract surgery*. CLIN OPHTHALMOL. 2019: 13: 2143-50.
[45] Clark DJ. *Simple non-opioid analgesia for cataract surgery*. Previously submitted to CMS.

These studies demonstrate that OMIDRIA leads to a decrease in opioid dependence and in postoperative prescription opioids, and further support CMS' proposal to continue the policy it established to incentivize the use of non-opioid pain management surgical drugs with the overall goal of combating the current opioid addition crisis. In addition, in the event that CMS were to decide to adopt an evidentiary standard consistent with the Agency's procedure of notice-and-comment rulemaking, these studies demonstrate that OMIDRIA would meet such standard.

VI. CONCLUSION

We appreciate CMS' ongoing efforts to reduce opioid dependency through payment policies that improve access to non-opioid alternatives. The nation's opioid epidemic has not subsided with the emergency of the COVID-19 pandemic, and many reports indicate that it has been exacerbated by the COVID-19 pandemic.

Omeros supports CMS' proposed continuation of its 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…."[46]

Based on the established regulatory criteria constituting CMS' payment policy for non-opioid pain management surgical drugs that are policy-packaged, CMS should confirm in the pending final rule that OMIDRIA qualifies to be unpackaged and separately paid when used in the ASC setting for CY 2021.

Thank you for your attention to this matter, and please do not hesitate to contact me should you require any additional information.

Sincerely,

Gregory A. Demopulos, M.D.
Chairman and Chief Executive Officer
Omeros Corporation

[46] 85 Fed. Reg. at 48979.