VOICES FOR NON-OPIOID CHOICES

September 17, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS- 1753-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted online via www.regulations.gov

RE: **CMS- 1753-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals**

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the proposed rule entitled, "Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals," as published in the *Federal Register* on August 4, 2021 (hereinafter referred to as the "Proposed Rule").

Our comments will specifically address many of the questions posed in the Proposed Rule on the benefits of nonopioid pain management approaches. Additionally, these comments will discuss the opportunity before the agency to address the nation's worsened opioid use disorder crisis by providing more fulsome access to the full range of FDA-approved, safe, and effective nonopioid based pain management approaches.

The Voices for Non-Opioid Choices coalition (hereinafter referred to as "Voices") represents many of the nation's leading public health advocacy, provider, recovery, and patient advocate voices from across the country. Members of Voices have come together around the shared priority of advancing federal policy approaches to preventing opioid use disorder in Americans, including by removing policy barriers that inhibit patient and provider access to nonopioid pain management approaches. To date, much of our work has focused on the unintended impact that payment policy has had on affording patients and providers access to **all** appropriate pain management approaches – opioid-based and nonopioid based – across **all** care settings, including the hospital outpatient department (HOPD) and ambulatory surgical center (ASC).

As such, our hope is that the Centers for Medicare & Medicaid Services (CMS) will effectuate a policy change that will allow for separate reimbursement for all FDA-approved, safe, and effective nonopioid based pain management approaches for HOPD patients, as it has already done for patients treated in an ASC. In doing so, CMS can dramatically increase utilization of nonopioid based pain management approaches and reduce the number of Americans who go on to long-term opioid use following a surgical procedure.[i]

To this end, in the proposed rule[ii] CMS acknowledges the impact that separate reimbursement can have on utilization of nonopioid pain management approaches. In the ASC setting, where these approaches are paid separately, CMS appropriately notes that utilization of these therapies increased 120 percent in just one year[iii]. Extending such a policy change to the HOPD setting would further increase access to and utilization of nonopioid pain management approaches for more patients and dramatically reduce rates of opioid use disorder in the United States.

Key Background Considerations

Every year, more than 3 million Americans go on to long-term opioid use following a surgical procedure.[iv] This represents approximately 9.2 percent of all outpatient surgery patients in any given year.[v] Opioid-based pain relief is currently the standard of care for these patients, as more than 90 percent of these patients[vi] receive some level of opioid-based pain relief.

Unfortunately, many of these patients receive copious amounts of opioids following a surgical procedure. On average, these patients receive more than 80 opioid pills to manage their postsurgical pain[vii]. Often, this level of opioid prescribing is well-above what is necessary to provide appropriate analgesia for these patients and is well-above international standards[viii]. It is accordingly hardly surprising to learn that the United States consumes approximately 80 percent of the world's supply of prescription opioid pills[ix], including nearly 90 percent of the world's prescription hydrocodone pills[x].

For many patients, their first exposure to opioids is following a surgical procedure and, for some, being prescribed opioids can carry with it disastrous long-term consequences associated with the potential of misusing these prescription pills or developing an opioid use disorder. Voices – and our 76 member organizations[xi] – believe that one way to stem these rates of long-term opioid use after surgery is to increase the availability of other, nonopioid based pain management approaches, including by facilitating access to these approaches through appropriate payment policy incentives. In doing so, CMS can minimize unnecessary exposure to prescription opioids and reduce the number of Americans who initiate long-term opioid use following a surgical procedure.

Finally, it is important to consider the current opioid use disorder environment in the United States, particularly in the context of the current COVID-19 pandemic. More than 95,000 Americans died of a drug related overdose in 2020[xii]. Approximately 71,000 of these overdose deaths involved opioids[xiii] meaning 195 Americans died every day[xiv] from an opioid-related drug overdose in 2020.

These never-before-seen levels of drug and opioid-related overdose deaths have shattered all previous records and represent a 30 percent increase since 2019[xv], which is also the largest single year increase in drug overdose deaths in more than two decades[xvi].

For context, when Voices launched in May of 2019[xvii], government data frequently cited 130 Americans who died of an opioid-related drug overdose[xviii]. All told, these numbers paint a

harrowing picture of the state of opioid use disorder in the United States – one where rates of opioid-related drug overdose increased by 50 percent in just 2 years[xix].

Despite these record-breaking numbers, CMS continues to unnecessarily expose patients to opioids by inhibiting patient and provider access to nonopioid pain management approaches, as a result of its asymmetrical site of care payment policies (ASC vs. HOPD).

Requested Feedback [from Proposed Rule]

In the proposed rule[xx], CMS requested feedback on several questions related to nonopioid based pain management and the impact that payment has on making such options available to patients and providers. Our comments will focus on the following questions: [from Proposed Rule[xxi]]

- *What is the clinical benefit to Medicare beneficiaries of separate reimbursement for nonopioid pain management approaches in the HOPD setting? [Page 26]*
- *What disincentives currently exist in the HOPD setting to using nonopioid pain management approaches? Are they the same (or similar) to those that have been previously identified as unique to the ASC (i.e. lesser reimbursement in the ASC, specialized care provided in the ASC, etc.)? [Page 26]*
- *Should FDA indication for pain management be a criterion? Should the eligibility requirements be the same in order to qualify for separate reimbursement in the HOPD and the ASC? Should utilization be part of the evaluation and determination of whether a nonopioid pain management product should qualify for separate payment? Should evidence of reduced opioid use be a consideration or criteria for separate reimbursement for nonopioid based pain management approaches? If so, how is that being measured (i.e. reduced opioid consumption, reduced rates of opioid use disorders, etc .) and how should that evidence be supported (e.g. in a peer reviewed publication)? [Pages 26-30]*
- *Application of these criteria to non-drug, nonopioid pain management approaches [Page 30]*

Clinical Benefit:

The clinical benefits of nonopioid based pain management approaches have been made abundantly clear through a bevy of peer-reviewed, published literature over the past several years. Increasing access to nonopioid therapies in the hospital setting will extend the following clinical benefits of meaningfully better health outcomes to these patients:

- Faster postsurgical recovery;

It is well-documented that patients treated with treatment plans prioritizing nonopioid approaches (e.g. multimodal approaches or enhanced recovery after surgery (ERAS) protocols) can significantly shorten hospital lengths of stay (LOS).

One such study[xxii] evaluating opioid use in patients undergoing radical cystectomy found that patients receiving nonopioid pain management approaches had a median LOS that was nearly 17 percent (or 1 day) shorter than patients receiving an epidural.

Another study evaluating the impact of nonopioid pain management approaches for patients undergoing total hip arthroplasty (THA) found similar results – average patient LOS was .7 days shorter in patients receiving nonopioid-based pain management approaches compared to those

receiving opioids[xxiii]. This study also concluded that total hospitalization costs for patients receiving nonopioid pain management approaches was $561 less than patients receiving opioids[xxiv].

Finally, a study looking at major colorectal surgeries found that average patient LOS was 1.8 days shorter in patients treated with nonopioid pain management protocols than those receiving opioids[xxv].

- Similar (or better) analgesic support;

Non-opioid pain management approaches have been demonstrated to be highly effective in providing analgesic support for patients. In some instances, patient-reported pain scores were, in fact, lower in patients receiving nonopioid pain management support[xxvi] when compared to those patients receiving opioids.

In fact, one study evaluating the impact of a breast surgery focused ERAS protocol in lumpectomy procedures found that nonopioid based pain management support was just as effective as the standard of care[xxvii], which included opioid-based pain relief. This study also noted that nonopioid pain management support in these patients eliminated the need for an opioid prescription at discharge[xxviii].

Colorectal patients receiving nonopioid pain management support have also reported significantly lower pain scores after surgery[xxix]. In one study, these patients reported pain scores that were 17 percent lower than patients receiving opioids[xxx].

- Reduced post-surgical opioid use;

According to the universe of peer-reviewed literature, one of the main clinical benefits of nonopioid based pain management support is that it can, in many cases, eliminate the need for postsurgical opioid prescriptions. One study found that utilization of a nonopioid pain management approach resulted in a 91 percent reduction of opioid consumption within 24 hours[xxxi] following a total knee arthroplasty (TKA).

Other studies largely support this claim, including:

- A study looking at third molar extraction, found that patients receiving nonopioid pain management support were prescribed 59 percent fewer opioids[xxxii];
- Patients undergoing colorectal surgeries and receiving nonopioid based pain management support consumed nearly 52 percent fewer opioids 72 hours after surgery than those receiving traditional care[xxxiii];
- Another analysis found that THA patients receiving nonopioid pain support consumed 73 percent fewer opioids 2 days following their procedure[xxxiv];
- TKA patients receiving nonopioid analgesic support were found to consume 78 percent fewer opioids 48-72 hours after surgery than those receiving opioids[xxxv]; and
- A study looking at patients undergoing cataract surgery who received a nonopioid pain management drug found a nearly 80 percent reduction in fentanyl use while also reducing patient-reported pain scores by approximately 50 percent[xxxvi].

- Fewer opioid-related adverse events (ORAE) and rehospitalizations

Opioids themselves carry specific therapeutic complications to patients. These challenges extend beyond potential risk for long-term use after initial exposure. These complications can range in scope and impact from digestive challenges[xxxvii] (e.g. nausea, vomiting, and/or constipation) to respiratory depression[xxxviii].

In some instances, patients require continued hospital supervision or are readmitted to hospitals following an ORAE. Accordingly, one benefit of increased utilization of nonopioid pain management approaches is reducing the number of ORAEs associated with prescribing patients opioids to manage their pain.

The literature on the topic is clear and compelling that use of ERAS and multimodal protocols is an effective way to limit ORAEs in surgical patients. Examples include a study examining the dangers of opioid-based pain therapy among elderly Americans who are at increased risk of suffering from an ORAE after surgery[xxxix] and another study that demonstrated that ORAEs rates are more than 50 percent lower in patients receiving multimodal pain management approaches[xl].

Setting of Care Barriers:

In the rationale for paying separately for nonopioid based pain approaches in ASCs, CMS pointed to a number of factors making ASCs unique from HOPDs, including, for example, lower ASC reimbursement rates. Similarly, there are a number of hospital-specific circumstances that have the unintended impact of limiting provider and patient access to nonopioid based therapies.

CMS notes, by way of an example, that ASCs receive approximately 55 cents for every dollar that a hospital receives for a procedure, which makes them more significantly impacted by delivery of more expensive services, including nonopioid pain approaches. On the other hand, many hospital systems – in order to abide by state and federal laws, meet requirements from the Joint Commission, and other mandates – have significantly more physical and care-related infrastructure, require substantially more staff, provide significantly more ancillary services, and have substantially higher overhead costs.

As a result, the costs of providing additional, higher-cost services – such as administering nonopioid pain management therapies – is just as challenging in the HOPD setting due to tight operating margins. For example, on average, hospital operating margins in the United States are approximately 2 percent as of April 2021[xli], with a wide degree of variation. Rural and safety net hospitals are struggling the most financially, with the least ability to make even small adjustments within a bundled payment environment as they operate, on average, with a margin that is a third that of other U.S. hospitals[xlii]. This inequity leaves Medicare beneficiaries at such institutions at a significant disadvantage in terms of access to non-opioids.

In an environment with razor-thin and tightening operating margins, the surgical supply packaging policy has a uniquely profound impact on treatments that add any cost to the hospital but are not paid separately – like nonopioid pain management approaches. Accordingly, given this environment and the broader worsened state of opioid use disorder in the United States, Voices believes that the HOPD setting is not well positioned to pay for the costs of higher cost options and requires separate reimbursement to be able to manage these costs.

Qualification and Eligibility Criteria:

The proposed rule lays out two new criteria for nonopioid approaches to qualify for separate reimbursement. One of these criteria requires these therapies to be FDA-approved and have a specific indication for pain management or analgesia.

This constitutes an objective, easy-to-apply eligibility criteria by referencing each product's FDA-approved label to determine eligibility for separate payment for nonopioid therapies in the ASC. [It would be a similarly easy to apply criteria should such a policy change be put forward for the HOPD setting.] Additionally, limiting separate reimbursement for nonopioid therapies to those with an FDA-approved indication for pain management or analgesia will ensure nonopioid products are safe and effective for the expanded use in the Medicare population that will result from separate payment.

Voices supports application of this proposed eligibility criterion across all setting of care (ASC and HOPD) for nonopioid approaches.

The Proposed Rule[xliii] also seeks comment as to whether specific evidence of reduced utilization should be part of the agency's evaluation and determination of whether a nonopioid pain management product should qualify for modified payment. Clinical decisions, including those related to pain management, are deeply complex and result from a number of factors at play. Part of the increased utilization of non-opioids in the ASC setting, as well as the marginal increase in utilization of non-opioids in the HOPD setting, could be the result of evolving clinical practice, growing recognition of the ongoing opioid use disorder epidemic in the country, and/or state-imposed opioid prescribing limits. Therefore, it is impossible to isolate the impact (or lack thereof) of the agency's payment policy. **CMS should not, at this time, adopt a utilization threshold for a nonopioid drug or device to qualify for separate payment.**

Finally, the Proposed Rule[xliv] seeks comment as to whether there should be any future additional eligibility requirements to qualify as a nonopioid pain management approach. One such criterion would be the ability of such products to reduce or eliminate or significantly reduce postsurgical opioid consumption. While measuring and demonstrating consumption reductions may prove challenging with existing data, Voices would propose that one such additional criterion could be for qualifying nonopioid approaches to **demonstrate the ability to replace, reduce, or avoid opioid use or the quantity of opioids prescribed**.

There are a number of studies (including those referenced above) that point to the benefits of multimodal pain management approaches. Each of these studies demonstrates a significant reduction in postsurgical opioid prescribing, including by as much as 91 percent for certain patients[xlv].

As a result, **Voices supports the addition of another criterion in future rulemaking proceedings to qualify as a nonopioid approach for separate payment to include the ability to replace, reduce, or avoid opioid use or the quantity of opioids prescribed, as demonstrated in a clinical trial or through data published in a peer-reviewed publication.**

Application for Non-Drug Approaches:

Voices believes that all, safe, effective, and evidence-based pain management services should be made available to acute pain patients. This includes all available pharmacologic, non-pharmacologic and therapeutic services.

Examples of such approaches could include (but is not limited to): non-steroidal anti-inflammatory drugs (NSAIDs), nerve blocks, medical devices such as stimulation machines and pain pumps, acupuncture, physical therapy, chiropractic services, and others.

Voices believes that the eligibility requirements for these services should be the same standard that the Proposed Rule[xlvi] uses for pharmacologic drugs. In doing so, CMS would not be perceived to give specific preference to any single nonopioid pain management approach.

Accordingly, Voices believes that for non-drug approaches to be applicable to receive separate payment, these services must meet a two-fold standard. Specifically, such services must utilize FDA-approved drugs or devices, and found to be safe and effective for the explicit purpose of providing analgesic support for acute pain patients **and** demonstrate the ability to significantly limit or eliminate the prescription of opioids as evidenced by publication in a peer-reviewed journal.

Other Considerations – Changes to the Inpatient Only (IPO) List

The Proposed Rule[xlvii] rolls back policy changes that went into effect earlier this year, which removed 298 codes from the IPO[xlviii]. This change – finalized in 2020 and effective January 1, 2021 – was a welcomed first step to migrate the provision of certain services from the HOPD to the ASC.

In the 2020 comment period, Voices was supportive of certain migration of care from the HOPD to the ASC, as long as the services are deemed to be able to be performed in a safe and effective manner in the ASC setting. Voices supported these changes because of the ability for ASCs to be reimbursed separately for the cost of administering nonopioid pain management services.

Accordingly, the rule was an opportunity to increase access to and utilization of nonopioid pain management services by migrating the care setting from an HOPD setting – where payment policy does not allow for access to nonopioid pain management approaches – to an ASC setting where patients are more likely to access nonopioid pain management approaches.

Voices is concerned that by rolling back this policy change, as the Proposed Rule[xlix] does, may unnecessarily expose HOPD patients to opioid-based pain approaches, which carry with them the risk for long-term opioid use, misuse, dependence and addiction.

The cited rationale for making this policy change was after a clinical review was performed of the 298 codes found that it would be more appropriate to shift these services back to the IPO. **To ensure transparency in this process and that relevant clinical voices are heard and considered, Voices respectfully requests the CMS publicly release the results of this clinical review and initiate a formal public review and comment period on whether these services and codes should be subjected to the IPO.**

Conclusion

Voices strongly encourages CMS to consider the opportunity before the agency – and the broader environment related to the opioid use disorder epidemic in the United States. CMS has the tools at its disposal to immediately reduce rates of opioid use disorder in the country and the associated overdose deaths.

Additionally, CMS has already identified a successful policy change that has been proven to dramatically increase access to and utilization of nonopioid pain management approaches. By

separately paying for nonopioid pain management approaches administered in the ASC setting, CMS has increased utilization of nonopioid approaches by 120 percent in that setting alone. However, this policy change needs to be extended to the HOPD setting to ensure site of care parity for outpatient surgical procedures.

Accordingly, Voices urges CMS to separately reimburse for nonopioid pain management approaches administered to patients on the HOPD setting. Voices believes that all available, safe, effective, and FDA-approved drugs, devices, and services that can demonstrate the ability to provide significant clinical benefit (including those that compare favorably to opioids), have been specifically indicated for providing acute pain analgesic support, and (in future iterations of this rule) have the ability to replace, reduce, or avoid opioid use or the quantity of opioids prescribed, as demonstrated in a clinical trial or through data published in a peer-reviewed publication should qualify for such separate payment.

***

On behalf of Voices, our member organizations, and the countless families who have lost loved ones to an opioid addiction that was initiated after being prescribed opioids after surgery, we thank you for your consideration of these comments.

If you have any questions about these comments, Voices, or our work, please do not hesitate to contact Chris Fox (chris@nonopioidchoices.org).

Sincerely,

Chris Fox
Executive Director

[i] Hah, J. M., Bateman, B. T., Ratliff, J., Curtin, C., & Sun, E. (2017). Chronic Opioid Use After Surgery: Implications for Perioperative Management in the Face of the Opioid Epidemic. Anesthesia and analgesia, 125(5), 1733–1740. Available at: https://doi.org/10.1213/ANE.0000000000002458.

[ii] 86 Fed. Reg. 42018 (Aug. 4, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-15496.pdf.

[iii] *Ibid.*

[iv] Hah, J. M., Bateman, B. T., Ratliff, J., Curtin, C., & Sun, E. (2017). Chronic Opioid Use After Surgery: Implications for Perioperative Management in the Face of the Opioid Epidemic. Anesthesia and analgesia, 125(5), 1733–1740. Available at: https://doi.org/10.1213/ANE.0000000000002458.

[v] *Ibid*.

[vi] Hill, M. V., McMahon, M. L., Stucke, R. S., & Barth, R. J., Jr (2017). Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures. Annals of surgery, 265(4), 709–714. Available at: https://doi.org/10.1097/SLA.0000000000001993.

[vii] Bicket, M., White, E., Wu, C., Pronovost, P., Yaster, M., & Alexander, G. (2017) (232) Prescription opioid oversupply following orthopedic surgery: A prospective cohort study. The Journals of Pain. 18 (4), S34. Available at: https://doi.org/10.1016/j.jpain.2017.02.124.

[viii] Duff, J, Tharakan, S., Davis-Castro, C.,Cornell, A., and Romero, P. (2021). Consumption of Prescription Opioids for Pain: A Comparison of Opioid Use in the United States and Other Countries. Congressional Review Service, 1-48. Available at: https://sgp.fas.org/crs/misc/R46805.pdf.

[ix] Manchikanti, L., & Singh, A. (2008). Therapeutic opioids: a ten-year perspective on the complexities and complications of the escalating use, abuse, and nonmedical use of opioids. Pain physician, 11(2 Suppl), S63–S88.
[x] *Ibid.*
[xi] Available at: https://nonopioidchoices.org/members/.
[xii] Ahmad FB, Rossen LM, Sutton P. (2021) Provisional drug overdose death counts. National Center for Health Statistics. Available at: https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm.
[xiii] *Ibid.*
[xiv] *Ibid.*
[xv] *Ibid.*
[xvi] *Ibid.*
[xvii] Available at: https://nonopioidchoices.org/wp-content/uploads/2019/08/FINAL-Voices-Press-Release-051619.pdf.
[xviii] Opioid Overdose Crisis. National Institute of Drug Abuse. Available at: https://www.drugabuse.gov/drug-topics/opioids/opioid-overdose-crisis.
[xix] *Ibid.*
[xx] 86 Fed. Reg. 42018 (Aug. 4, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-15496.pdf.
[xxi] *Ibid.*
[xxii] Chu, C. E., Law, L., Zuniga, K., Lin, T. K., Tsourounis, C., Rodriguez-Monguio, R., Lazar, A., Washington, S. L., 3rd, Cooperberg, M. R., Greene, K. L., Carroll, P. R., Pruthi, R. S., Meng, M. V., Chen, L. L., & Porten, S. P. (2021). Liposomal Bupivacaine Decreases Postoperative Length of Stay and Opioid Use in Patients Undergoing Radical Cystectomy. Urology, 149, 168–173. Available at: https://doi.org/10.1016/j.urology.2020.11.036.
[xxiii] Asche, C. V., Dagenais, S., Kang, A., Ren, J., & Maurer, B. T. (2019). Impact of liposomal bupivacaine on opioid use, hospital length of stay, discharge status, and hospitalization costs in patients undergoing total hip arthroplasty. Journal of medical economics, 22(12), 1253–1260. Available at: https://doi.org/10.1080/13696998.2019.1627363.
[xxiv] *Ibid.*
[xxv] Beck, D. E., Margolin, D. A., Babin, S. F., & Russo, C. T. (2015). Benefits of a Multimodal Regimen for Postsurgical Pain Management in Colorectal Surgery. The Ochsner journal, 15(4), 408–412.
[xxvi] Weir, T. B., Simpson, N., Aneizi, A., Foster, M. J., Jauregui, J. J., Gilotra, M. N., Henn Iii, R. F., & Hasan, S. A. (2020). Single-shot liposomal bupivacaine interscalene block versus continuous interscalene catheter in total shoulder arthroplasty: Opioid administration, pain scores, and complications. Journal of orthopaedics, 22, 261–267. Available at: https://doi.org/10.1016/j.jor.2020.05.006.
[xxvii] Rojas, K. E., Manasseh, D. M., Flom, P. L., Agbroko, S., Bilbro, N., Andaz, C., & Borgen, P. I. (2018). A pilot study of a breast surgery Enhanced Recovery After Surgery (ERAS) protocol to eliminate narcotic prescription at discharge. Breast cancer research and treatment, 171(3), 621–626. Available at: https://doi.org/10.1007/s10549-018-4859-y.
[xxviii] *Ibid.*
[xxix] Beck, D. E., Margolin, D. A., Babin, S. F., & Russo, C. T. (2015). Benefits of a Multimodal Regimen for Postsurgical Pain Management in Colorectal Surgery. The Ochsner journal, 15(4), 408–412.
[xxx] *Ibid.*
[xxxi] Dysart, S. H., Barrington, J. W., Del Gaizo, D. J., Sodhi, N., & Mont, M. A. (2019). Local Infiltration Analgesia With Liposomal Bupivacaine Improves Early Outcomes After Total Knee Arthroplasty: 24-Hour Data From the PILLAR Study. The Journal of arthroplasty, 34(5), 882–886.e1. Available at: https://doi.org/10.1016/j.arth.2018.12.026.
[xxxii] Lieblich, S. E., Misiek, D., Olczak, J., Fleck, H., & Waterman, F. (2021). A Retrospective Cross-Sectional Study of the Effect of Liposomal Bupivacaine on Postoperative Opioid Prescribing After Third Molar Extraction. Journal of oral and maxillofacial surgery : official journal of the American Association of Oral and Maxillofacial Surgeons, 79(7), 1401–1408.e1. Available at: https://doi.org/10.1016/j.joms.2021.02.012.
[xxxiii] Beck, D. E., Margolin, D. A., Babin, S. F., & Russo, C. T. (2015). Benefits of a Multimodal Regimen for Postsurgical Pain Management in Colorectal Surgery. The Ochsner journal, 15(4), 408–412.
[xxxiv] Asche, C. V., Ren, J., Kim, M., Gordon, K., McWhirter, M., Kirkness, C. S., & Maurer, B. T. (2017). Local infiltration for postsurgical analgesia following total hip arthroplasty: a comparison of liposomal bupivacaine to

traditional bupivacaine. Current medical research and opinion, 33(7), 1283–1290. Available at: https://doi.org/10.1080/03007995.2017.1314262.

[xxxv] Mont, M. A., Beaver, W. B., Dysart, S. H., Barrington, J. W., & Del Gaizo, D. J. (2018). Local Infiltration Analgesia With Liposomal Bupivacaine Improves Pain Scores and Reduces Opioid Use After Total Knee Arthroplasty: Results of a Randomized Controlled Trial. The Journal of arthroplasty, 33(1), 90–96. Available at: https://doi.org/10.1016/j.arth.2017.07.024.

[xxxvi] Donnenfeld ED, Shojaei RD. Effect of intracameral phenylephrine and ketorolac 1.0%/0.3% on intraoperative pain and opioid use during cataract surgery. Clin Ophthalmol. 2019;13:2143–2150.

[xxxvii] Stratton, M., Waite, P. D., Powell, K. K., Scopel, M. M., & Kukreja, P. (2021). Benefits of the enhanced recovery after surgery pathway for orthognathic surgery. International journal of oral and maxillofacial surgery, S0901-5027(21)00161-2. Advance online publication. Available at: https://doi.org/10.1016/j.ijom.2021.04.008.

[xxxviii] Radke, J. B., Owen, K. P., Sutter, M. E., Ford, J. B., & Albertson, T. E. (2014). The effects of opioids on the lung. Clinical reviews in allergy & immunology, 46(1), 54–64. Available at: https://doi.org/10.1007/s12016-013-8373-z.

[xxxix] Halaszynski T. (2013). Influences of the aging process on acute perioperative pain management in elderly and cognitively impaired patients. The Ochsner journal, 13(2), 228–247.

[xl] Yalmanchili, H. M., Buchanan, S. N., Chambers, L. W., Thorns, J. D., McKenzie, N. A., Reiss, A. D., Page, M. P., Dizon, V. V., Brooks, S. E., Shaffer, L. E., Lovald, S. T., Hartranft, T. H., & Price, P. D. (2019). Postlaparotomy pain management: Comparison of patient-controlled analgesia pump alone, with subcutaneous bupivacaine infusion, or with injection of liposomal bupivacaine suspension. Journal of opioid management, 15(2), 169–175. Available at: https://doi.org/10.5055/jom.2019.0498.

[xli] Paavola, A., (2021). Margins remain narrow for US hospitals. Beckers Healthcare. Available at: https://www.beckershospitalreview.com/finance/margins-remain-narrow-for-us-hospitals.html.

[xlii]Gee, G. (2019) The High Price of Hospital Care. Center for American Progress. Available at: https://www.americanprogress.org/issues/healthcare/reports/2019/06/26/471464/high-price-hospital-care/.

[xliii] 86 Fed. Reg. 42018 (Aug. 4, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-15496.pdf.

[xliv] *Ibid.*

[xlv] Dysart, S. H., Barrington, J. W., Del Gaizo, D. J., Sodhi, N., & Mont, M. A. (2019). Local Infiltration Analgesia With Liposomal Bupivacaine Improves Early Outcomes After Total Knee Arthroplasty: 24-Hour Data From the PILLAR Study. The Journal of arthroplasty, 34(5), 882–886.e1. Available at: https://doi.org/10.1016/j.arth.2018.12.026.

[xlvi] 86 Fed. Reg. 42018 (Aug. 4, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-15496.pdf.

[xlvii] *Ibid.*

[xlviii]Centers for Medicare & Medicare Services. Trump Administration Finalizes Policies to Give Medicare Beneficiaries More Choices around Surgery. CMS. Available at: https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-policies-give-medicare-beneficiaries-more-choices-around-surgery.

[xlix] 86 Fed. Reg. 42018 (Aug. 4, 2021) available at https://www.govinfo.gov/content/pkg/FR-2021-08-04/pdf/2021-15496.pdf.