



# AMERICA'S ESSENTIAL HOSPITALS

September 17, 2021

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue SW  
Washington, DC 20201

**Ref: 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 submit comments on the above-captioned proposed rule. America's Essential Hospitals appreciates the Centers for Medicare & Medicaid Services' (CMS') work to improve the delivery of high-quality, integrated health care across the continuum. We are deeply concerned about several provisions of the proposed rule that exceed the agency's statutory authority and would have a disproportionately negative impact on essential hospitals, which are committed to combating inequities that lead to health disparities among underrepresented populations. The steep cuts to hospitals in the 340B Drug Pricing Program, coupled with the cuts to off-campus provider-based departments (PBDs), will impede the ability of essential hospitals to remain financially solvent and continue to serve as the primary point of care for underserved communities, including people of color disproportionately affected by public health crises such as the COVID-19 pandemic. Further, given the current surge of COVID-19 cases and the resource strain on hospitals, CMS' ill-timed proposal to increase penalties for noncompliance with price transparency requirements would be especially detrimental to hospitals already in a tenuous financial situation.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Essential hospitals provide state-of-the-art, patient-centered care while operating on margins one-third that of other hospitals—2.9 percent on average compared with 8.8 percent for all hospitals nationwide.<sup>1</sup> These narrow operating margins result in minimal reserves and low cash on hand—circumstances exacerbated by financial pressures related to COVID-19.

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<sup>1</sup> Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2019 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2021. <https://essentialdata.info>. Accessed August 27, 2021.

Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and more than 22 million live below the poverty line.<sup>2</sup> Essential hospitals are uniquely situated to target these social determinants of health (SDOH) and are committed to serving these marginalized patients. These circumstances, however, compound our members' challenges and strain their resources, requiring flexibility to ensure essential hospitals are not unfairly disadvantaged for serving marginalized populations and can continue to provide vital services in their communities.

Essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. These ambulatory networks are a central part of essential hospitals' efforts to address the structural racism ingrained in the health care system at large by bringing culturally competent care to patients who otherwise lack access to care. These networks allow essential hospitals to bring care closer to where their patients live, which is an important step in ensuring continuity of care for patients whose health is shaped by lack of transportation, unstable housing, and other social risk factors. Our members provide comprehensive ambulatory care through networks of hospital-based clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

These ambulatory networks also are a critical asset in essential hospitals' response to COVID-19. They have enabled essential hospitals on the front lines to screen, test, and treat COVID-19 patients in their communities.

We are pleased by CMS' proposal to halt the removal of the inpatient-only (IPO) list and look forward to engaging with the agency to advance policies that ensure patient safety while being responsive to innovations in the outpatient setting. Other proposed policies, however, would further exacerbate essential hospitals' uncertain financial future. Continuing reduced payment to office visits at excepted off-campus PBDs will severely limit the ability of essential hospitals to provide comprehensive, coordinated care to disadvantaged populations. CMS' inequitable policy to reduce Part B drug payments to hospitals treating disproportionate numbers of low-income patients already has severely impacted essential hospitals; it undermines these providers' ability to offer heavily discounted drugs to patients in the face of rapidly increasing drug prices. In our detailed comments below, we urge CMS to withdraw its PBD and 340B payment proposals.

- 1. For calendar year (CY) 2022, CMS should pay hospitals in the 340B program the statutory default payment of average sales price (ASP) plus 6 percent. CMS' proposed payment methodology exceeds the agency's statutory authority and undermines the Public Health Service Act (PHSA), and the cuts to 340B hospitals have irreparably harmed low-income patients and the hospitals committed to treating them.**

**America's Essential Hospitals implores CMS to withdraw its proposed continuation of this policy because the payment cut is based on an unlawful**

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<sup>2</sup> Ibid.

**application of CMS’ authority to set payment rates for specified covered outpatient drugs (SCODs) under the Social Security Act (SSA) and has had devastating consequences for underserved communities.** For the fifth straight year, CMS proposes to reimburse certain separately payable drugs purchased through the 340B program at 77.5 percent of ASP. This policy represents a nearly 30 percent reduction in payments from the statutory default methodology for hospitals in the 340B program, while hospitals not in the program continue to receive payment at 106 percent of ASP. By ending these cuts to safety net providers once and for all, the agency will be acting in alignment with the Biden administration’s priorities of addressing health inequities and promoting the health of the nation’s marginalized communities.

As CMS notes in the proposed rule, Congress created the 340B program, codified in the PHSA, to allow covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>3</sup> Under the 340B program, covered entities can purchase certain outpatient drugs at discounted prices, enabling savings critical to the operations of hospitals that fill a safety net role. These savings also enable essential hospitals to address the social determinants shaping their patients’ health, such as food insecurity, homelessness, and lack of transportation. Essential hospitals reinvest 340B savings into programs to coordinate care and improve outcomes for disadvantaged populations, including initiatives to reduce readmissions, ensure medication compliance, and identify high-risk patients in need of ancillary services. The 340B program is structured by statute to offer hospitals discounts for covered outpatient drugs provided to patients of a covered entity, regardless of a patient’s insurance status. Congress plainly expected that various public and private payers would reimburse hospitals at rates higher than the cost of the discounted drugs they receive from manufacturers, which is how hospitals were expected to stretch resources to expand access to medications and other vital services, as explained in our comments below.

For the fifth consecutive year, we urge the agency to reverse Part B payment cuts to 340B hospitals. Continuing with these steep payment cuts to hospitals an additional year, particularly during a pandemic, is ill-advised and detrimental to hospitals and their patients. In the five years since CMS first proposed this sweeping policy change, the agency has yet to demonstrate that the policy lowers drug prices, financially helps beneficiaries, or improves access to or quality of care for Medicare beneficiaries. On the contrary, as we establish in more detail in the following sections, CMS’ drug reimbursement policy already has undermined a key policy lever that has proved effective in combating high drug prices and protecting hospitals that treat high numbers of low-income patients.

- a. CMS’ payment methodology under the Medicare statute conflicts with another statute, the PHSA, and undermines Congress’ intent in enacting the 340B program.

By substantially altering Medicare reimbursement for 340B hospitals, CMS undermines the intent of section 340B of the PHSA. While the 340B program is not under CMS’ purview, the Department of Health and Human Services (HHS) has an obligation under principles of statutory interpretation to implement the Medicare statute in a way that does not conflict with or undermine another program and its statutory intent, to the extent possible.<sup>4</sup> CMS’ policy prior to 2018 aligns with this premise, demonstrating it is possible to implement a reasonable interpretation of Medicare rate-setting authority consistent with 340B program intent. Despite CMS’ assertions, the policy to reduce 340B hospital drug reimbursement is inconsistent with and undermines the purposes of the 340B program.

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<sup>3</sup> H.R. Rep. No. 102–384, pt. 2 (1992).

<sup>4</sup> See, e.g., Statutory Interpretation: General Principles and Recent Trends (December 19, 2011) at page 29.

As CMS notes in the preamble of the proposed rule, “By design, the 340B Program increases the resources available to these safety net providers by providing discounts on covered outpatient drugs that generate savings that can be used to support patient care or other services. When the program was created, there was an understanding that many of the patients seen by these safety net providers were Medicare and Medicaid beneficiaries.”<sup>5</sup> We agree the 340B program was designed to allow covered entities to realize savings and increase their resources, which in turn can be directed to treating underserved patients. CMS’ proposal to continue the current policy, which reduces payments to 340B hospitals by nearly 30 percent, conflicts with this interpretation of the 340B statute. Congress specifically designated which safety net providers should benefit from the program, defining eligible disproportionate share hospitals as those serving a disproportionately greater percentage of low-income patients (determined through Medicaid and Medicare Supplemental Security Income). Congress intended these hospitals to receive discounted drugs and expected them to stretch their resources, including Medicare reimbursement, to continue caring for low-income patients—among them, vulnerable Medicare beneficiaries.

By reducing reimbursement and minimizing the benefit of the program, these cuts contradict the intent of the program. In a recent legal filing, the administration described the intended operation of the program, which allows providers to “generate much-needed revenue through sale of those drugs (particularly to patients who are insured) or pass along the discounts directly to patients. The 340B Program has served a crucial role in facilitating healthcare for vulnerable patients ever since.”<sup>6</sup> The drastic reduction in the payment rate undercuts the ability of hospital serving these vulnerable patients to realize these savings and remain financially solvent.

Further, by redirecting these funds intended for 340B hospitals to other hospitals in the Medicare program, CMS’ policy violates the intent of the 340B program. Not only has CMS’ policy cut into the scarce resources of hospitals specified in statute, but the agency’s budget neutrality adjustment redistributes these funds to hospitals not in the 340B program. In essence, CMS is redirecting payment for 340B drugs to hospitals excluded from the program. Hospitals treating fewer low-income patients benefit at the expense of hospitals serving marginalized patients. This is clearly not what Congress intended when it enacted the 340B program.

- b. CMS’ drug payment policy harms essential hospitals and their low-income patients while doing nothing to counter astronomically rising drug prices.

**Since CMS implemented this policy, which has reduced drug payments to 340B hospitals by more than \$6.5 billion over four years, the agency has not provided evidence that the policy has improved access to and quality of health care or benefited Medicare beneficiaries.** CMS has not analyzed whether the policy has met its intended goals, how it has affected patient access, whether it has lowered drug prices, or how it has affected hospital operations. In fact, drug prices have continued to rise since implementation of the policy and hospitals continue to see their operations affected by their declining outpatient margins. The payment cuts also undermined the ability of hospitals to reinvest their 340B savings into initiatives combating structural racism and promoting health equity.

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<sup>5</sup> CY 2022 OPPTS Proposed Rule. 86 Fed. Reg. 42018, 42134. August 4, 2021.

<sup>6</sup> Government’s Brief in Support of Motion to Dismiss. AstraZeneca Pharmaceutical LP v. Xavier Becerra, et al. U.S. District Court for the District of Delaware. C.A. No. 21-27-LPS. May 4, 2021.

It is especially troubling that CMS would continue these payment cuts already totaling in the billions of dollars during a pandemic, which has strained hospital operations and finances. During the COVID-19 pandemic, hospitals on the front lines of response efforts have experienced tens of billions of dollars in lost revenue and increased expenses per month. On top of the losses hospitals incurred in 2020, hospitals could lose an additional \$100 billion in the aggregate in 2021.<sup>7</sup> These financial losses associated with the pandemic have been more pronounced for nonprofit hospitals compared with for-profit hospitals. It would be devastating for these public and nonprofit 340B hospitals to face an additional \$2 billion in Medicare cuts in 2022 on top of the hundreds of billions of dollars in losses they have experienced due to the pandemic. The brunt of these cuts will be felt by low-income and other disadvantaged people who rely on 340B hospitals for their care.

By adversely targeting hospitals treating low-income patients, CMS' cuts impede the progress of 340B hospitals in addressing upstream factors that negatively affect health and in promoting health equity. Our hospitals use 340B savings to invest in programs targeting SDOH. For example, 340B savings enable some essential hospitals to offer housing assistance and care managers; medication management therapy and post-discharge counseling that helps reduce readmissions and improve medication adherence; and low-cost or no-cost drugs. Other essential hospitals invest 340B savings in school-based health centers in low-income communities and operate medical home programs for low-income and uninsured patients, which helps to reduce emergency department (ED) use. Cuts to 340B savings undermine these types of initiatives and threaten to set back progress toward health equity. Reversing the cuts would allow hospitals to continue to invest their savings in these important programs, aligning with the Biden administration's emphasis on promoting health equity and tackling health disparities.

As America's Essential Hospitals has expressed in its comments in previous years, in addition to being unlawful and undercutting health equity initiatives, the 340B payment cut is a counterproductive policy for several reasons:

- The cuts jeopardize the patchwork support on which essential hospitals rely, threatening their ability to maintain critical services. 340B hospitals' Medicare outpatient margins are substantially lower than non-340B hospitals. Accounting for the reduced Outpatient Prospective Payment System (OPPS) reimbursement resulting from the Part B payment reduction, 340B hospitals' Medicare outpatient margins would drop even further by an additional three percentage points. At the same time, because of the redistributive, budget-neutral nature of the policy, non-340B hospitals will see their Medicare outpatient margins increase by three percentage points;
- Patients do not benefit from CMS' payment cuts. Because CMS implements this policy in a budget-neutral manner that raises OPPS rates for other ambulatory payment classifications, all beneficiaries pay higher copays for other services. Additionally, most beneficiaries have some form of third-party coverage that covers unpaid Medicare copays; and
- The payment cuts undermine the administration's efforts to counter astronomically rising drug prices. While the evidence is clear that drug list prices have risen from year to year, CMS provides no evidence of how lowering reimbursement to 340B hospitals for separately payable drugs under the OPPS would counter this trend. The 340B

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<sup>7</sup> King R. Hospital could lose between \$53B and \$122B this year due to pandemic. *Fierce Healthcare*. February 24, 2021. <https://www.fiercehealthcare.com/hospitals/kaufman-hall-hospitals-close-between-53-and-122b-year-due-to-pandemic>. Accessed August 27, 2021.

program actually saves money for providers, patients, and the federal government. It is a critical tool that insulates patients from rising drug prices and ensures their continued access to needed therapeutics.

It is difficult to justify this policy, which reduces the benefit of the 340B program, while threatening the ability of participating hospitals to provide care to marginalized Medicare beneficiaries and other patients. The reduction in payments to 340B hospitals has had negative consequences for essential hospitals and their patients; therefore, **we strongly urge the agency to withdraw this policy once and for all and revert to paying 340B hospitals at 106 percent of ASP.** We believe preserving the intent of the 340B program would better serve low-income Medicare beneficiaries and the Medicare program at large, while aligning with the policy goals of this administration.

- c. CMS' proposed policy violates the plain language of the SSA and is impermissible under the Administrative Procedure Act (APA).

**CMS should reverse its policy of reducing payments for separately payable drugs purchased through the 340B program because it is inconsistent with the agency's statutory authority under the SSA.** CMS should revert to its statutory default methodology, under which it paid all hospitals before the CY 2018 OPPS final rule. America's Essential Hospitals continues to challenge the lawfulness of these cuts in the courts, in a case that the Supreme Court recently agreed to review. As America's Essential Hospitals has argued in depth in previous comment letters and in court filings, CMS' reduced reimbursement rate for 340B drugs contravenes the Medicare statute. More specifically, CMS lacks the authority for the payment cut because:

- CMS' policy is an unlawful departure from the statutory default payment for separately payable Part B drugs, which requires the agency to pay at ASP plus 6 percent if it does not have acquisition cost data;
- CMS' nearly 30 percent payment cut to a specific subset of hospitals does not constitute an "adjustment" under section 1883(t)(14)(A)(iii)(II) of the SSA. The adjustment is excessive and would have to be applied to all OPPS hospitals, not just one subset of hospitals;
- CMS cannot attempt to pay at acquisition cost when it lacks acquisition cost data and has been paying under the ASP methodology in section 1833(t)(14)(A)(iii)(II); and
- CMS' payment methodology conflicts with another statute, the PHSA, and undermines Congress' intent in enacting the 340B program. By redirecting funds intended for 340B hospitals to other hospitals in the Medicare program, CMS' policy violates the intent of the 340B program.

Given that the policy is under review by the Supreme Court, implementing it for another year not only will impede hospital operations and patient access but also impose an unnecessary burden on the agency and hospitals if the court invalidates this policy. Hospitals will continue to be underpaid for another year, while the agency will have to reverse course and implement a remedy to make hospitals whole after its cuts begin for 2022.

- 2. CMS should not reduce payments for separately payable drugs purchased through the 340B program and administered at non-excepted PBDs, as doing so exceeds the agency's statutory authority under the SSA.**

CMS proposes to continue its unlawful payment policy for 340B drugs to non-excepted PBDs, as it did for the first time in CY 2019. Specifically, the agency plans to pay at 77.5 percent of ASP

for 340B drugs administered in non-excepted off-campus PBDs under section 603 of the Bipartisan Budget Act of 2015 (BBA). These PBDs are not paid for outpatient services at the full OPPS rate but instead under the Medicare Physician Fee Schedule (PFS), as adjusted. As we argue above, the policy to reimburse for 340B drugs at 77.5 percent of ASP under the OPPS is unlawful under the SSA. Extending this policy to non-excepted PBDs is equally untethered from the statute, which also precludes payment at a rate other than 106 percent of ASP for these clinics in these ways:

- The Medicare PFS is the applicable payment system for non-excepted PBDs, and it requires payment for drugs at 106 percent of ASP under section 1842(o)(1)(c);
- This section does not contain adjustment authority similar to section 1833(t)(14)(A)(iii) and therefore bars CMS from paying anything other than 106 percent of ASP; and
- From a policy standpoint, CMS' and Congress' rationale for reducing payment to off-campus PBDs is to equalize payment with physician offices. If that is the desired goal, CMS should pay hospital off-campus PBDs at 106 percent of ASP—the same as it pays physician offices. Instead, CMS wants to pay these off-campus PBDs even less than physician offices. This policy choice is out of line with the rationale behind the agency's site-neutral payment policy.<sup>8</sup>

For these reasons, CMS should pay non-excepted PBDs at 106 percent of ASP under the PFS payment methodology for separately payable drugs.

### **3. CMS should withdraw its proposal to continue reducing payments for clinic visits at excepted off-campus PBDs, as doing so reduces underserved patients' access to lifesaving services.**

As mandated by Section 603 of the BBA, CMS discontinued paying certain off-campus PBDs under the OPSS on January 1, 2017; the statute instructs CMS instead to pay these PBDs under another Part B “applicable payment system.” In CY 2017 OPSS rulemaking, CMS decided non-excepted PBDs would be paid under the Medicare PFS. The BBA clearly defines which PBDs would be affected by the law and specifically exempts other types of PBDs from changes in reimbursement. Since CY 2019, CMS has cut payment for outpatient clinic visits to excepted PBDs, which are clearly outside the reach of the reduced payment amount under Section 603. These visits, assigned Healthcare Common Procedure Coding System code G0463, are the most frequently performed service in the outpatient setting and encompass visits from the most basic patients to those with multiple chronic conditions seeking care from specialists. Outpatient clinic visits are necessary to coordinate care, reduce readmissions, and keep patients out of the ED.

CMS' proposal to continue to reduce payment for outpatient clinic visits at excepted PBDs to 40 percent of the OPSS rate has and will continue to undermine the ability of essential hospitals to serve marginalized populations in underserved areas. Many essential hospitals have off-campus clinics in federally designated areas with shortages of providers, including health professional shortage areas and medically underserved areas. Further, these clinics are more likely to serve patients dually eligible for Medicare and Medicaid, as well as uninsured patients and those on Medicaid, compared with freestanding physician offices. Off-campus PBDs also serve a higher

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<sup>8</sup> For additional discussion of these legal arguments, see America's Essential Hospitals Comment Letter on CY 2020 OPSS Proposed Rule. September 27, 2019. <https://essentialhospitals.org/wp-content/uploads/2019/09/FINAL-AEH-CY2020-OPSS-Comment-Letter-9-27-19-for-archive.pdf>. Accessed August 27, 2021.

proportion or racial and ethnic minorities compared with freestanding physician offices.<sup>9</sup> These clinics have faced severe cuts due to CMS' policy, threatening their closure and restricting access to care for communities in which access to health care already is limited and cannot be provided by freestanding physician offices. **We urge the administration to swiftly end this policy once and for all by reverting to the full OPPI payment rate for these excepted clinics.**

**4. CMS should implement Section 603 of the BBA consistent with the legislative text to minimize the adverse effect on patient access.**

In drafting the BBA, Congress left some specifics of Section 603 implementation for CMS to clarify through the rulemaking process. However, in its interpretation, the agency unnecessarily expanded the law's scope beyond Congress' legislative text and original intent; this will further harm essential hospitals and the marginalized patients they serve. **CMS should use its statutory authority to offer flexibility and reduce burden on providers, particularly regarding relocation and change of ownership.**

- a. CMS should allow PBDs to retain their excepted status notwithstanding relocation.

**CMS should allow PBDs to retain their excepted status, even if they relocate, if they continue to meet the provider-based requirements.** In the CY 2017 OPPI final rule, CMS created a limited extraordinary circumstances exception that allows a PBD to temporarily or permanently relocate without forfeiting excepted status. However, the exceptions process only covers a few scenarios and does not envision the many reasons for which a PBD might need to relocate. The BBA neither contemplated nor required that PBDs would lose their excepted status if they relocated.

There are many external forces that could compel a hospital to relocate a clinic. One of the most glaring examples has been the need for hospitals to relocate PBDs during the COVID-19 pandemic to increase access for patients and to triage care. In recognition of the need for hospitals to relocate PBDs during the pandemic, CMS allowed on-campus PBDs and excepted off-campus PBDs to relocate while maintaining their excepted status during the COVID-19 public health emergency (PHE). However, this relocation exception is temporary, and CMS will require hospitals to move the PBD back to its original location once the COVID-19 PHE expires. To allow hospitals to meet the needs of their communities and to respond to potential outbreaks of COVID-19, or other public health crises, in the future, CMS should allow hospitals to permanently relocate their PBDs once the COVID-19 PHE expires if it is in the best interests of their patients and communities.

There are other reasons a hospital might need to relocate its PBDs. For example, when a provider's lease for a PBD expires, it might find the renewal terms unsustainable. As landlords realize that CMS policy effectively makes a PBD a captive audience, they are likely to raise the rent. While any reasonable business facing such unfavorable economic conditions would consider relocation as a response, a PBD might simply close, given the lack of a financially viable alternative under the proposed relocation policy. Other reasons for relocation beyond a provider's control could include a building being closed for reconstruction or demolition, local zoning changes or ordinances, or other state and local laws. CMS' limitation on relocation is guided by the agency's belief that hospitals are motivated only by financial considerations. As

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<sup>9</sup> *Comparison of Care in Hospital Outpatient Departments and Independent Physician Offices*. American Hospital Association. April 2021. <https://www.aha.org/guidesreports/2021-04-14-comparison-care-hospital-outpatient-departments-and-independent-physician>. Accessed August 27, 2021.



these examples show, there are many reasons a provider might have to relocate that fall outside the agency's narrow exception.

**For these reasons, CMS should lift the burdensome limitation on relocation and clarify that a hospital can relocate an excepted PBD if it continues to meet the provider-based requirements.**

- b. CMS should permit non-excepted PBDs to retain their excepted status if they change ownership.

In the CY 2017 OPSS final rule, CMS finalized a policy that allows a PBD to maintain excepted status only if the main provider that owns the PBD changes ownership and the new main provider accepts the existing Medicare provider agreement. In scenarios in which the main provider does not change ownership but an individual PBD does, CMS states the PBD would lose its excepted status. **We recommend that CMS extend the policy on changes of ownership to circumstances in which an individual PBD changes ownership.** It is not uncommon for provider-based facilities to change hands over time for various reasons. For example, a hospital that finds operating an off-campus PBD unsustainable for financial or other reasons might decide to sell that particular PBD. But if the loss of excepted status makes the PBD unattractive to potential buyers, the hospital might close it. In such a case, patients in the community would lose access to vital outpatient services. Because excepted PBDs that change ownership operated before the date of enactment and are not newly created, they should remain excepted.

##### **5. Communities served by essential hospitals face unique health and social challenges; CMS should account for these challenges and preserve adequate reimbursement rates for essential hospitals' excepted and non-excepted PBDs.**

We urge the agency to reverse course on the expansion of site-neutral payment policies to excepted PBDs, which disproportionately affect essential hospitals and the patients they serve. To align with the administration's policy goals, the agency must revise its policy in a way that protects essential hospitals and their patients, rather than causing further harm. Essential hospital PBDs are disproportionately impacted by site-neutral payment policies. For hospitals operating on narrow (often negative) margins, these substantially lower payments are unsustainable and will affect patient access in areas with the greatest need for these services. Essential hospitals operate on a negative 16 percent Medicare outpatient margin—9 percentage points lower than OPSS hospitals nationally. Continuing these cuts for an additional year would reduce essential hospitals' outpatient margins by an additional four percentage points. **If CMS does not reverse course on the extension of its site-neutral policy to clinic visits at excepted off-campus PBDs, we strongly urge CMS to exclude excepted PBDs of essential hospitals from the reduced payment rate. Additionally, CMS should pay non-excepted PBDs of essential hospitals subject to Section 603 at a rate no lower than 75 percent of the OPSS rate.** Doing so would ensure essential hospital PBDs can continue to cover the costs associated with providing comprehensive, coordinated care to complex patient populations in underserved areas and advance the administration's health equity goals. America's Essential Hospitals stands ready to work with CMS to identify reliable data sources that can be used to identify hospitals caring for a disproportionate share of low-income beneficiaries and fulfilling a safety net mission in their communities.

Given essential hospitals' expansive networks of ambulatory care in otherwise underserved communities, site-neutral payments will continue to have a profound negative effect on their patients. In most communities, essential hospitals are the only providers willing to take on the

financial risk of providing comprehensive care to low-income patients, including the uninsured and dual-eligible beneficiaries. PBDs enable hospitals to expand access for disadvantaged patients in communities with no other options for both basic and complex health care needs. Essential hospital PBDs often are the only clinics in low-income communities that provide full primary and specialty services.

CMS' site-neutral payment policies have played an undeniable role in limiting health care access for the country's most disadvantaged patients and will only further exacerbate health disparities. Essential hospitals are committed to advancing the Biden administration's goal of advancing racial equity throughout the federal government, including by addressing health disparities.<sup>10</sup> The patients treated at essential hospitals' off-campus PBDs typically are low-income people and people of color. Compared with patients at other hospitals, a significantly higher proportion of patients treated at essential hospital PBDs are dually eligible for Medicare and Medicaid, which is a key indicator of patient complexity. Dual-eligible beneficiaries tend to be in poorer health status, more likely to be disabled, and costlier to treat compared with other Medicare beneficiaries.<sup>11</sup> In fact, CMS uses a hospital's proportion of dual-eligible beneficiaries as a proxy for adjusting the hospital readmission measures to recognize differences in sociodemographic factors. Excessively burdensome and restrictive policies on essential hospitals' PBDs undoubtedly have downstream effects, including limiting patient access.

Essential hospital clinics often fill a void by providing the only source of primary and specialty care in their communities. Because of their integrated health systems, essential hospitals can help drive down overall health care costs, including for the Medicare program, by efficiently providing coordinated care through ambulatory networks. Providing care in the outpatient setting allows hospitals to avoid unnecessary ED visits, manage patients with chronic conditions, provide follow-up care to patients to avoid readmissions, and, in the process, reduce costs for the health care system at large. These are goals CMS should promote—not stifle—through policies that protect patient access to vital clinic visits in essential hospital PBDs.

**6. CMS should halt elimination of the IPO list, add back the services removed in 2021, and further engage stakeholders in the development of a strategy for future removal of procedures from the IPO list. This strategy should ensure patient safety and account for impacts to patient-mix in Medicare payment models.**

Procedures on the IPO list usually are performed only in the inpatient setting and are reimbursed at inpatient rates—not paid for under the OPPS. Each year, CMS reviews this IPO list for procedures that should be removed because they can be provided in the outpatient setting.

In the CY 2021 OPPS final rule, CMS finalized elimination of the IPO list in its entirety (all 1,740 services) by January 1, 2024. As part of a three-year transition period, the agency identified 298 musculoskeletal services, such as hip and knee arthroplasty and spine procedures, for removal in CY 2021.

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<sup>10</sup> Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. January 20, 2021. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>. Accessed August 27, 2021.

<sup>11</sup> Medicare Payment Advisory Commission. Data Book: Health Care Spending and The Medicare Program. July 2020. [http://www.medpac.gov/docs/default-source/data-book/july2020\\_databook\\_entirereport\\_sec.pdf](http://www.medpac.gov/docs/default-source/data-book/july2020_databook_entirereport_sec.pdf). Accessed August 27, 2021.

- a. CMS should finalize its proposal to halt the elimination of the IPO list and add back the 298 procedures removed from the list in CY 2021.

In prior comments to CMS, America's Essential Hospitals voiced concerns about the potential for unintended consequences associated with eliminating the IPO list, as well as the proposed three-year time frame for removal. The sweeping change raised patient safety concerns and would have created complexity and confusion for providers in their clinical decision-making. Further, removal of 298 services in 2021 represented the largest one-time removal of services from the IPO list. **We strongly support CMS' proposal to halt elimination of the IPO list and to add back the 298 procedures removed in CY 2021.**

- b. CMS should maintain the IPO list and work with stakeholders to develop a strategy for future removal of services, based on current standard of practices.

America's Essential Hospitals supports the goal of providing more choice to patients and providers regarding the care setting. However, increased access to care should not jeopardize care quality. Along with physician judgment, the IPO list serves as a tool to indicate which services are appropriate to furnish in the outpatient setting. **We urge CMS to study the differences in performing procedures in both settings to ensure patient safety for all Medicare beneficiaries.**

Prior to CY 2021, changes to the IPO list were gradual. We support this thoughtful approach and **urge CMS to continue to use the longstanding criteria for removing services from the IPO list**, including the systematic evaluation of each service before proposing to remove it.

Further, when services are removed from the IPO list, providers need time to prepare clear criteria for surgical site selection, develop criteria for patient selection, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the Inpatient Prospective Payment System (IPPS) or OPPS. **We encourage CMS to provide adequate time and guidance to providers before removing a procedure from the IPO list.**

- c. CMS should examine the effect of removing services from the IPO list on current Medicare payment models to ensure patient safety is maintained and hospitals are not negatively impacted.

We continue to have concerns about the effect of removing services in current Medicare payment models from the IPO list. In comments to CMS on its removal of the total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedures, we noted that these services on the IPO list are included in two episode-based payment models: Comprehensive Care for Joint Replacement (CJR) and Bundled Payment for Care Initiative (BPCI). In the BPCI and CJR models, services are paid on a fee-for-service basis with retrospective reconciliation against target prices based on historical costs associated with the procedure, for a defined time period. Being that TKA/THA was on the IPO list, we raised concern to CMS that the agency did not have claims history for beneficiaries receiving these procedures on an outpatient basis.

As CMS contemplates future removal of procedures from the IPO list, we urge the agency to consider patients who previously would have received procedures included in Medicare models in an inpatient setting that may receive those procedures on an outpatient basis if eliminated from the IPO list. This potential shift in care setting complicates the process for establishing an accurate target price based on historical data within CMS models. Further, the historical episode spending data might not accurately predict episode spending for beneficiaries receiving

the procedure as an inpatient. **Removing procedures from the IPO list will require modifications to the current Medicare payment models**, leading to confusion among hospitals and CMS, as well as issues of accuracy and fairness in setting target prices. **We urge CMS to further examine the impact on Medicare models to ensure hospitals are not negatively impacted** by removal of services from the IPO list.

Additionally, in many cases, there are differences in patient population for procedures performed on an outpatient basis—i.e., younger, active, fewer complications, and having more support at home than most Medicare beneficiaries. Further, many Medicare patients have comorbidities and require intensive rehabilitation after a certain procedures (e.g., TKA/THA), best performed in an inpatient setting. As such, certain procedures performed on an outpatient basis might only be appropriate for a small number of Medicare beneficiaries. We encourage CMS to work with stakeholders to identify a methodology for payment model participants that appropriately adjusts target prices for inpatient procedures to reflect the shift of less complex procedures to the outpatient setting. **We urge CMS to study the differences in performing procedures in both settings to ensure patient safety and fairness among participants in episode-based payment models, before removing services from the IPO list.**

- d. CMS should provide a three-year exemption from the two-midnight rule for procedures removed from the IPO list.

The two-midnight rule states Medicare will only consider an inpatient admission appropriate for Part A reimbursement when the admitting practitioner expects a patient will require a stay in the hospital exceeding two midnights. If the clinician does not believe the patient needs care expected to exceed two midnights, the practitioner should not admit the patient, unless there is an exception documented in the medical record that demonstrates the need for inpatient care. America's Essential Hospitals previously noted its objections to the two-midnight policy and emphasized the need to allow physicians to base decisions on genuine medical need and not arbitrary, time-based presumptions. The two-midnight policy also caused confusion and added additional administrative burden for hospital staff. CMS made changes to the two-midnight rule in past years that are positive steps toward preserving clinician judgment and addressing these concerns.

We appreciate CMS' recognition of the need to exempt procedures recently removed from the IPO list from medical review under the two-midnight rule. **However, we urge the agency to increase the grace period for procedures removed from the IPO list to three years.** Specifically, CMS proposes procedures it removes from the IPO list would not be subject to referrals to Recovery Audit Contractors (RACs) and would not be subject to patient status reviews by RACs for two calendar years after removal from the IPO list. Further, CMS would not deny claims for patient status for procedures within the first two years of their removal from the IPO list—that is, it would not deny inpatient payment for a procedure removed from the IPO list that did not meet the two-midnight rule. Beneficiary and family-centered care quality improvement organizations, which are the first entities to review claims for compliance with the two-midnight policy, would only review claims for educational purposes during this two-year grace period.

Because procedures on the IPO list can only be performed in the inpatient setting, they are an exception to the two-midnight rule. However, once they are removed from the IPO list, they can be provided in the outpatient setting and would be reviewed under the two-midnight rule, except for during CMS' proposed two-year grace period. CMS should increase the grace period to three years to allow hospitals and practitioners sufficient time to adjust their billing and

clinical systems, as well as processes used to determine the appropriate setting of care. Because providers have no experience assessing procedures on the IPO list against the two-midnight benchmark (since they previously could only be performed in the inpatient setting), they will require time to update their procedures to make appropriate decisions about whether to admit patients for procedures recently removed from the IPO list.

**7. CMS should delay implementing increased penalties related to the hospital price transparency requirements, given the current surge of COVID-19 and resource strain on hospitals, and further refine the penalty formula to ensure fairness across hospitals.**

In the CY 2020 Hospital Price Transparency final rule, effective Jan. 1, CMS established enforcement policies, including a process for monitoring hospital compliance with price transparency requirements and a civil monetary penalty (CMP), not in excess of \$300 per day, that may be imposed on a hospital if it fails to respond to CMS' request to submit a corrective action plan or comply with the terms of such a plan. The agency previously stated the \$300 maximum daily amount is reasonable because "noncompliance is less serious than noncompliance that poses or results in harm to the public."

Based on its initial months of experience with enforcing the price transparency rule, CMS is concerned about what it deems a "high rate of hospital noncompliance." The agency seeks to adjust the penalties moving forward, to be "more relevant to the characteristics of the noncompliant hospital." CMS proposes to use a scaling factor to establish the CMP amount for a noncompliant hospital. The scale would range from \$300 to \$5,500 per hospital, with CMP amounts established based on the noncompliant hospital's number of beds, as specified in hospital cost report data submitted to CMS. **We oppose an increase in CMP amounts and encourage CMS to work with hospitals to comply with all aspects of the price transparency rule.**

In the proposed rule, CMS discusses other potential scaling factors considered, but not proposed, beyond bed count. If CMS finalized an increase in CMP amounts, there are other factors that should be considered. For example, a hospital may have invested already scarce resources to implement a comprehensive cost estimation tool that provides useful information that empowers consumers to make informed decisions about their care. Another hospital could be successfully integrating cost estimation tools into daily operations and workflows and ensuring patients facing social risk factors, such as limited English proficiency, receive cost information in a culturally competent way.<sup>12</sup> While it would require additional effort on the part of CMS to ensure consistency in application, **tailoring the amount of the CMP to account for unique hospital circumstances would achieve a level of fairness not found in the proposed use of bed count alone.**

CMS proposes an effective date of Jan. 1, 2022, for the modifications to the CMP amounts. Hospitals nationwide continue to respond to the surge in COVID-19 cases tied to the delta variant and low vaccination rates. Resources and attention are justifiably focused on educating communities about the importance of vaccination, while simultaneously providing acute care to those infected with the virus. These efforts are precisely for the prevention of harm to the public. Further, as noted by CMS, noncompliance with the price transparency rule does not pose or result in harm to the public. **We urge CMS to delay the effective date of the**

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<sup>12</sup> Schwartz R, Guinan M, Jimenez K. Price Transparency: Ensuring Useful Information for Patient Care Decisions. February 2020. <https://essentialhospitals.org/wp-content/uploads/2020/01/Price-Transparency-Brief.pdf>. Accessed August 26, 2021.

**changes to CMP amounts for the later of either one year (i.e., Jan. 1, 2023) or the end of COVID-19 PHE.**

**8. CMS should incentivize use of non-opioid alternatives by paying for them separately.**

In the proposed rule, CMS seeks comment on Medicare packaging policies for non-opioid alternative treatments. Specifically, CMS seeks comment on extending to the hospital outpatient setting its ambulatory surgical center (ASC) policy of paying separately for non-opioid medications considered supplies to a surgical procedure. Essential hospitals are national leaders in reducing opioid dependence through the implementation of clinical practices that encourage the use of non-opioid alternative treatments. An essential hospital in New Jersey was the first hospital to develop an alternatives-to-opioids program in its ED that prioritizes the use of non-opioid treatments to manage acute pain. In the first two years of the program, the hospital decreased opioid prescriptions by 82 percent while continuing to meet patients' needs for pain relief for ailments such as renal colic pain, sciatica, headaches, musculoskeletal pain, and extremity fractures. These non-opioid treatments include other medications, ultrasound-guided nerve blocks, nitrous oxide, and trigger-point injections. While this essential hospital and others are developing pioneering approaches to combat the opioid crisis, there are prevailing cost and payment barriers to the use of non-opioid alternatives; CMS can reduce such barriers to encourage the adoption of these alternative treatments.

CMS currently pays separately for two non-opioid alternatives—Exparel and Omidria—in the ASC setting. Because they receive separate payment, they receive payment at 106 percent of ASP instead of being paid as part of the surgical payment. The agency seeks comment on paying separately for these and any additional non-opioid pain management drugs in the hospital outpatient setting. Packaging a supply into payment for an overall surgical procedure results in underpayment for the supply. When a hospital receives a single, packaged payment for a surgical procedure, the payment rate is based on the average cost of providing the surgery and the associated bundle of services across all hospitals. Packaged payment does not account for the higher costs of an individual service or supply, such as a non-opioid alternative, at a given hospital. In many cases, the cost of a non-opioid alternative is prohibitive and is more than the cost of a comparable opioid treatment. **To eliminate this issue, we urge CMS to establish parity between the ASC and OPFS payment policies for these drugs by separately paying for Exparel, Omidria, and other non-opioid alternative treatments and to discontinue packaging these treatments into payment for the surgical procedure. Further, CMS should ensure these drugs are paid at the full statutory default payment rate of 106 percent of ASP, regardless of whether they are administered at a 340B hospital.**

As essential hospitals have demonstrated, non-opioid alternatives often are effective tools for pain management. In instances for which a non-opioid treatment is clearly preferable to an opioid-based treatment, there are payment and cost barriers that discourage the use of such alternative methods. Outside the limited scope of packaging policies, CMS should work to ensure adequate payment for non-opioid alternatives and develop policies that counter rising drug prices. In addition to inadequate Medicare payment, the rising cost of drug list prices strains hospital budgets. For example, intravenously administered acetaminophen often is a viable alternative to opioids, but the list price increase of this drug might discourage some providers from using it, especially if the comparable opioid is more affordable. Ultrasound-guided nerve blocks and compartment blocks, likewise, are insufficiently reimbursed. **CMS should evaluate its payment policies to ensure sufficient payment for non-opioid alternative treatments, while simultaneously working with stakeholders to address the root causes of rising drug list prices.**

**9. CMS should provide clear definitions and measure specifications before requiring reporting of the COVID-19 vaccination among health care personnel (HCP) measure. The agency also should streamline vaccination-related reporting by hospitals and seek National Quality Forum (NQF) endorsement of the measure.**

Essential hospitals continue to educate staff and their communities about the importance of vaccination in the fight against COVID-19, particularly given the rise of cases tied to the delta variant and low vaccination rates. Most recently, America's Essential Hospitals, along with other hospital associations, called for its member hospitals to require their employees be vaccinated.<sup>13</sup>

CMS notes the importance of hospital outpatient departments reporting HCP vaccination information to assess whether these facilities are taking steps to limit the spread of COVID-19 among their health care workers. As such, CMS proposes to adopt a COVID-19 vaccination coverage among health care personnel measure in the Hospital Outpatient Quality Reporting (OQR) Program, beginning with the CY 2024 payment determination. The measure would assess the proportion of a hospital's health care workforce that has been vaccinated against COVID-19. Hospitals would collect data for the COVID-19 HCP vaccination measure for at least one self-selected week during each month of the reporting quarter and submit the data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network. CMS proposes that each quarter, CDC would calculate a single COVID-19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. If finalized, CMS would publicly report this rate each quarter.

This measure was recently adopted for the Hospital Inpatient Quality Reporting (IQR) Program in the FY 2022 IPPS final rule. Data collection begins Oct. 1 in the IQR Program. For the OQR Program, CMS would require hospitals to report data on the HCP measure quarterly, beginning in January 2022.

Since publication of the IPPS final rule, we have heard from essential hospitals about the lack of clarity in definitions required for implementation of this measure. For example, how to define health care personnel eligible to work at the facility. Given the complex and varied employment arrangements—including volunteers, medical students, temporary staff, and contract personnel—**it is critical CMS swiftly provide guidance and support to essential hospitals as they prepare for data collection and reporting in October.** In many cases, these essential hospitals are in crisis mode, contending with yet another surge in COVID-19 cases amid a workforce shortage. There also are unknown factors that could complicate measure data collection, such as future Food and Drug Administration approval of booster shots for the general adult population and specific recommendations from the CDC Advisory Committee on Immunization Practices for administering additional doses. **We urge CMS to work with CDC to provide clear definitions of measure specifications, including a “completed vaccination course.”**

The COVID-19 HCP vaccination coverage measure has not been submitted to NQF for endorsement. The Measures Application Partnership (MAP) Hospital Workgroup noted several factors related to the measure that merit consideration, including well-documented evidence,

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<sup>13</sup> America's Essential Hospitals Urges Members to Require Employee Vaccination. America's Essential Hospitals. July 21, 2021. <https://essentialhospitals.org/general/americas-essential-hospitals-urges-members-require-employee-vaccination/>. Accessed August 26, 2021.

finalized specifications, testing, and NQF endorsement.<sup>14</sup> **We urge CMS to seek NQF endorsement of the COVID-19 vaccination coverage among HCP measure.**

Additionally, hospitals report weekly to HHS the number of COVID-19 vaccine doses administered to health care personnel and patients. This reporting is entered through HHS' outside vendor, Teletracking. Alternatively, hospitals may submit data to their state (if properly certified) and the state reports on the hospital's behalf to the federal government.<sup>15</sup> **We urge CMS to issue clear guidance to hospitals on the various reporting requirements to HHS, CDC, and states and to minimize duplication of efforts and confusion.**

**10. CMS should further examine ways to address health equity in the Hospital OQR Program, including stratifying measure performance by social risk factors beyond dual eligibility, refraining from the public reporting of results that use indirect estimation for race and ethnicity, and supporting existing best practices in the collection of demographic data.**

As providers of care for marginalized and underrepresented communities, essential hospitals deeply understand the need to identify gaps in care quality that exist and to eliminate disparities as a matter of public health. It is critical that health equity is integrated and aligned across CMS programs. We applaud the Biden administration's emphasis on health equity and CMS' ongoing efforts to evaluate appropriate initiatives to reduce health disparities, including the request for comment on potential future efforts to address health equity in the Hospital OQR Program. America's Essential Hospitals and its members are committed to tackling these important topics and look forward to opportunities for ongoing stakeholder engagement.

- a. CMS should continue to refine its disparity methods by seeking further stakeholder input on OQR measures in these reports, including social risk factors beyond dual eligibility. The agency also should refrain from publicly reporting results that use indirect estimation for race and ethnicity.

The CMS disparity methods reports provide hospital-level confidential results stratified by dual eligibility (i.e., patients eligible for both Medicaid and Medicare) for the six condition-specific readmission measures in the Hospital Readmissions Reduction Program. CMS seeks comment on stratifying performance results in the hospital outpatient setting; the agency proposes to stratify the results using dual eligibility as a proxy for social risk.

CMS has identified six priority measures in the Hospital OQR Program as candidates for disparities reporting stratified by dual eligibility, including:

- MRI Lumbar Spine for Low Back Pain (OP-8);
- Abdomen CT—Use of Contrast Material (OP-10);
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery (OP-13);
- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy (OP-32);
- Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy (OP-35);
- and

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<sup>14</sup> Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. [http://www.qualityforum.org/Project\\_Pages/MAP\\_Hospital\\_Workgroup.aspx](http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx). Accessed June 7, 2021.

<sup>15</sup> COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting. Department of Health and Human Services. May 27, 2021. <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>. Accessed August 26, 2021.



- Hospital Visits after Hospital Outpatient Surgery (OP–36).

CMS notes the choice of these measures was based on “evidence of existing disparities, procedure volume, and statistical reliability.” The methodology to identify existing disparities and the threshold for procedure volume are unclear. We urge CMS to be transparent in its selection process for the disparity reports and to provide opportunity for stakeholder feedback in identifying measures that would benefit from stratification and confidential reporting.

Following potential confidential reporting using dual eligibility as a proxy for social risk, CMS is exploring the possibility of further expanding stratified reporting to include race and ethnicity. CMS currently does not consistently collect self-reported race and ethnicity data for the Medicare program. As such, the agency proposes to use indirect estimation of race and ethnicity to overcome current limitations of demographic information.

Indirect estimation of race and ethnicity often uses a combination of other data sources predictive of self-identified race and ethnicity, such as language preference, administrative records, first and last names matched to validated lists of names correlated to specific national origin groups, and the racial and ethnic composition of the surrounding neighborhood.

America’s Essential Hospitals appreciates CMS’ work to ensure transparency on disparities in health care and improve care for patients with social risk factors. However, we are concerned about the use of indirectly estimated race and ethnicity data in reporting disparity methods results and the unintended consequences if this information is publicly reported—for instance, the statistical uncertainty of this approach and the risk that consumers will rely on inaccurate results when making important care decisions. **We also encourage CMS to examine social risk factors beyond dual eligibility and race and ethnicity, such as community-level impacts (e.g., area deprivation index), to inform hospital efforts to identify disparities.**

- i. CMS should refrain from publicly reporting disparity methods results that use indirectly estimated race and ethnicity data.

Essential hospitals are committed to transparency and accuracy in quality measurement. Our members understand the importance of quality improvement reporting, especially with increasing demands for accountability, movement toward value-based purchasing, and growing consumer engagement. Our members also know the importance of sound data to reduce disparities in care, and they lead efforts to close gaps in quality for people of color.

CMS notes indirect estimation of race and ethnicity is “an intermediate step, filling the pressing need for more accurate demographic information” and that “self-reported race and ethnicity data are the gold standard for classifying an individual according to race or ethnicity.” Further, the agency acknowledges the limitations of using indirect estimation, including inaccuracies in certain geographies or populations.

In November 2020, the Urban Institute held a virtual workshop on the ethics of using imputation and related methods to fill missing race and ethnicity data for various datasets. Among the ethical risk areas raised during the workshop was the power dynamic between individuals whose data are collected and organizations collecting and using the data, such that communities of color are prevented from exercising ownership over their own data. The workshop participants also highlighted the degree of statistical uncertainty that comes from using imputation and related methods and the risk of “misinformed policy choices that harm [Black, Indigenous, and other people of color].” In particular, the level of variability is higher

for smaller race and ethnicity subgroups because fewer observations are imputed.<sup>16</sup> **CMS should further examine the unintended consequences of using indirect estimation of race and ethnicity data and seek stakeholder feedback on mechanisms that promote patient self-reported data among hospitals.**

Hospitals should be armed with as much meaningful information as possible to inform their decision-making and quality improvement efforts. The CMS disparity methods reports enable hospitals to internally examine their efforts to address disparities in the context of other hospitals in their region. Essential hospital leaders deeply understand the characteristics of the populations their hospitals treat and the challenges they face and are the best audience to view and interpret these reports. Publicly posting results using a method with potential variability and inaccuracy could lead to consumer confusion and would be a misrepresentation of care quality. **We strongly urge CMS to refrain from publicly posting disparity methods results that use indirect estimation of race and ethnicity.**

- ii. CMS should examine social risk factors, beyond dual eligibility and race and ethnicity, to capture the full array of variables that might impact quality of care.

America's Essential Hospitals previously expressed concern that the HRRP and other CMS programs unduly penalize hospitals that serve the nation's underrepresented populations because they fail to account for external factors that explain higher readmission rates. We are pleased the HRRP now includes peer grouping based on a hospital's proportion of dually eligible patients. However, as we have noted, this is only the first step toward true risk adjustment for hospitals treating patients facing social and economic challenges.

While we appreciate the conceptual basis for expanding the disparity methods by stratifying results by race and ethnicity, in addition to dual eligibility, this risk factor is limited in scope and flawed in approach. CMS should consider additional factors, such as the importance of screening for health literacy and communicating with at-risk patients and their caregivers, as well as integrating community and health care resources in care coordination after discharge. However, the disparity methodology fails to incorporate factors beyond dual-eligible status and race and ethnicity. Identifying which social risk factors might drive outcomes and how best to measure and incorporate those factors into payment systems is a complex task, but doing so is necessary to ensure better outcomes, healthier populations, lower costs, and transparency. **We urge CMS to further examine data sources and methods to capture social risk factors in a uniform way that can be used in future reporting of disparities.**

- b. CMS should promote culturally appropriate collection of patient race, ethnicity, and language (REL) data and information on other social risk factors in a standardized and useful way to help identify disparities and target improvement activities to achieve equity.

We applaud CMS' efforts to learn about facilities' current demographic data collection practices and potential challenges to collection of a minimum set of demographic data elements. America's Essential Hospitals encourages the collection of patient demographic data in a culturally sensitive and linguistically appropriate manner. Limited documentation of REL and SDOH data hinders our capacity to understand and adequately address social barriers to positive health outcomes.

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<sup>16</sup> Randall M, Stern A, Su Y. Five Ethical Risks to Consider before Filling Missing Race and Ethnicity Data, Workshop Findings on the Ethics of Data Imputation and Related Methods. Urban Institute. March 2021. [https://www.urban.org/sites/default/files/publication/103830/five-ethical-risks-to-consider-before-filling-missing-race-and-ethnicity-data-workshop-findings\\_o.pdf](https://www.urban.org/sites/default/files/publication/103830/five-ethical-risks-to-consider-before-filling-missing-race-and-ethnicity-data-workshop-findings_o.pdf). Accessed August 26, 2021.

Essential hospitals' commitment to caring for *all* people has made them providers of choice for patients of virtually every ethnicity and language. In 2019, more than half of discharges at essential hospitals were people of color.<sup>17</sup> America's Essential Hospitals and its members continually advance work to improve cultural competency, increase health literacy, and provide communication and language assistance. By involving the patient as an active participant in their care, hospitals can better assist patients in identifying care choices, as well as clinical and social needs that might improve health outcomes.

America's Essential Hospitals supports CMS' efforts to gather accurate, standardized information on patient demographic data. In 2011, the association partnered with other industry leaders in the National Call to Action to Eliminate Health Care Disparities, which promotes the culturally appropriate collection of patient REL information. We believe the collection of REL data supports hospitals' efforts to identify preferences and needs and to tailor a care plan to specific patient characteristics. For example, collecting preferred language helps identify appropriate interpreter services, as necessary. The ability to monitor and stratify data also helps front-line staff identify problems and standardize efforts across hospitals. As noted by CMS, "[c]omprehensive patient data on race, ethnicity, language, and disability status are key to identifying disparities in quality of care and targeting quality improvement interventions to achieve equity."<sup>18</sup> For example, one essential hospital in South Carolina gave patients the ability to add or edit sensitive information, such as gender self-description, through their secure online patient portal. **CMS should encourage efforts to collect demographic data in a culturally appropriate and standardized way.**

The unconscionable rates of COVID-19 infections and deaths among Black, Latino, and other populations have emphasized the need for collection and analysis of data by race, ethnicity, and preferred spoken and written language of patients. Further, the COVID-19 pandemic has shown that pervasive disparities only deepen during times of crisis. A CDC study of characteristics associated with hospitalization among patients with COVID-19 found a higher rate of COVID-19 hospitalizations among Black people. The agency noted these higher rates "might indicate that Black persons are less likely to be identified in the outpatient setting, potentially reflecting differences in health care access or utilization or other factors not identified through medical record review."<sup>19</sup> Data are critical to understanding the unique challenges and disparities patients face. While some data collection efforts in COVID-19 legislative packages sought to deepen our understanding of these disparities and their root causes, it is clear that more can and should be done to ensure all Americans have equitable access to high-quality care.

America's Essential Hospitals also supports efforts to improve the collection of SDOH information to better understand how these factors impact outcomes; this work is important in identifying the needs of our nation's underrepresented patients. **We support a consensus-building approach that brings interested stakeholders together to determine relevant social factors and how to capture them in a standardized, culturally sensitive way.** However, there are challenges to collecting SDOH data, including the sensitive nature of these conversations, a lack of alignment across screening tools, and a need to link data from medical and nonmedical sources (i.e., community services).

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<sup>17</sup> Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2019 Annual Member Characteristics Survey*. America's Essential Hospitals. May 2021. [www.essentialdata.info/](http://www.essentialdata.info/). Accessed August 26, 2021.

<sup>18</sup> Centers for Medicare & Medicaid Services. *Inventory of Resources for Standardized Demographic and Language Data Collection*. March 2020. <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf>. Accessed August 26, 2021.

<sup>19</sup> Killerby ME, Link-Gelles R, Haight SC, et al. *Characteristics Associated with Hospitalization Among Patients with COVID-19—Metropolitan Atlanta, Georgia, March–April 2020. Morbidity and Mortality Weekly Report*. June 17, 2020.

[https://www.cdc.gov/mmwr/volumes/69/wr/mm6925e1.htm?s\\_cid=mm6925e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6925e1.htm?s_cid=mm6925e1_w). Accessed August 26, 2021.

Since 2015, providers have been able to use Z codes—a subset of ICD-10 codes—to capture social determinant information for Medicare FFS beneficiaries. An analysis from CMS found less than 2 percent of Medicare FFS beneficiaries in 2017 had a Z code associated with a claim.<sup>20</sup> By encouraging the collection of these data in a standardized manner, CMS can help ensure essential hospitals have the resources necessary to address the adverse impact social barriers have on health. For example, in the FY 2020 IPPS rule, CMS recommended changing the severity level designation of the ICD-10 code for homelessness (Z59) from a noncomorbid condition to a comorbid condition. CMS cited data suggesting when the Z59 diagnosis code is reported as a secondary diagnosis, the resources involved in caring for the patient justify increasing the severity level. CMS chose not to finalize this policy. We encourage the agency to further examine these types of coding and payment adjustments available through existing mechanisms.

When equipped with proper data, essential hospitals can innovate and collaborate with community partners to mitigate health disparities, improve outcomes, and reduce health care costs. For example, essential hospitals in Pennsylvania teamed up with schools and community organizations to form the North Philadelphia Health Enterprise Zone (HEZ). The initiative, launched in 2016, focuses on four key factors: health, community, education, and technology. Hospitals in the region struggled to share data across different EHR platforms. Hospitals supporting the HEZ now participate in the regional health information exchange, HealthShare Exchange, which allows real-time information sharing among care providers, reducing unnecessary or repeat procedures and driving down hospital costs. In fact, Pennsylvania recently made a financial investment in this collaborative to support HEZ efforts on employment and housing protections—activities that can help mitigate barriers to care and reduce disparities.<sup>21</sup> **We urge CMS to support existing best practices in data collection and sharing of meaningful data as a critical step in eliminating health disparities.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or [eomalley@essentialhospitals.org](mailto:eomalley@essentialhospitals.org).

Sincerely,

Bruce Siegel, MD, MPH  
President and CEO

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<sup>20</sup> Z Codes Utilization among Medicare Fee-for-Service (FFS) Beneficiaries in 2017. CMS Office of Minority Health. January 2020. <https://www.cms.gov/files/document/cms-omh-january2020-zcode-datahighlightpdf.pdf>. Accessed August 26, 2021.

<sup>21</sup> George J. State invests \$4 million in North Philadelphia's Health Enterprise Zone. *Philadelphia Business Journal*. October 18, 2019. <https://www.bizjournals.com/philadelphia/news/2019/10/18/state-invests-4-million-in-north-philadelphia-s.html>. Accessed August 26, 2021.