



February 19, 2019

Re: CMS-9926-P

Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services PO Box 8016 Baltimore, MD 21244-8016

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020

Dear Administrator Verma:

On behalf of nearly 38,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the proposed 2020 Notice of Benefit and Payment Parameters (NBPP). Specifically, we would like to address some of the questions and proposals related to price transparency, as well as a few other policies proposed in the NBPP and finalized in previous notices and guidance documents that have a significant impact on the coverage of emergency services and access to care for higher risk populations.

Price Transparency

Overview

In the Executive Summary of the NBPP, CMS includes a short section that highlights some of the agency's ideas of how to improve transparency in the healthcare marketplace. Before responding to some of the specific concepts that CMS raises, ACEP would like to point out some factors and principles of transparency that are unique to emergency medicine. Like you, we strongly believe that a patient's concern should be focused on receiving the appropriate care, rather than choosing their care based on cost. In the emergency department (ED), minutes and seconds matter and emergency physicians are often required to exercise their best clinical judgment quickly. Patients who have life-threatening illnesses and injuries obviously cannot shop around for the "lowest cost" provider.

Furthermore, in delivering acute care, knowing what patients' total out-of-pocket costs will be before they are diagnosed and stabilized is nearly impossible until a proper course of medical care and progression is followed. A large proportion of emergency care involves the acute diagnosis, treatment, and stabilization of diffuse and undifferentiated

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clinical conditions. For example, two of the most common patient presentations are "chest pain" and "abdominal pain." These initial symptoms have a large range of ultimate diagnoses and require a large variety of patient-specific lab tests, radiology exams, and other interventions. This is very different from being able to figure out total costs for an urgent care patient with a small, clean, superficial laceration or a sore throat. Further complicating the issue is the fact that emergency care is billed in two separate components, the facility fee, and the professional fee. Therefore, patients must sort through costs included in at least two different bills, each of which may have different cost-sharing obligations associated with it.

The Emergency Medical Treatment and Labor Act (EMTALA)

Another major factor that affects price transparency for emergency care is the Emergency Medical Treatment and Labor Act (EMTALA). This cornerstone law guarantees access to emergency medical care for everyone, regardless of insurance status or ability to pay. The requirements of EMTALA are mandatory and are unaffected by in-network or out-of-network insurance status or payment considerations. EMTALA stipulates that a hospital may not place any signs in the emergency department regarding prepayment of fees or payment of copays and deductibles which can have the chilling effect of dissuading patients from "coming to the emergency department." To do so could lead patients to leave prior to receiving a medical screening examination and stabilizing treatment without regard to financial means or insurance status, which is a fundamental condition for satisfying EMTALA, and one of the most foundational principles of important patient protection that was enacted three decades ago. If we attempt to provide pricing information to patients prior to stabilizing them, not only would that be an EMTALA violation, but it could also potentially cause the patient's health to deteriorate since it could delay the patient from receiving critical care. The last thing we want to do is put our patients in a position of making life-or-death health care decisions based on costs.

"Prudent Layperson Standard" (PLP)

Beyond EMTALA, there is another essential protection that helps ensure that people can go to the ED without worrying about whether the services they receive will be covered by their insurance. A provision in federal law called the "Prudent Layperson Standard" (PLP) states that payers must cover any medical condition "manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in 1) placing the health of the individual (or a pregnant woman or her unborn child) in serious jeopardy; 2) serious impairment to bodily functions, or 3) serious dysfunction of any bodily organ or part." First established under the Balanced Budget Act of 1997, the PLP originally applied to all of Medicare and Medicaid managed care plans, and then was extended under the ACA to all insurance plans regulated under the Employee Retirement Income Security Act of 1974 (ERISA) and qualified health plans in the state Exchanges. Furthermore, 47 states (all except Mississippi, New Hampshire, and Wyoming) have passed their laws making some kind of prudent layperson standard mandatory in their state.

Over the last several years, private insurers (including QHPs) have begun once again to curtail patient access to emergency department care in violation of the PLP. Anthem plans in seven states (Missouri, Kentucky, and Georgia, Ohio, New Hampshire, and Indiana) are retroactively denying coverage for an emergency visit based on the final diagnosis, not the presenting symptoms. This includes the QHP products Anthem has in many of these states. In fact, during the second half of 2017, Anthem denied more than 12,000 claims (or approximately 5.8 percent of total ED claims) from patients in Missouri, Kentucky, and Georgia on the grounds that their

visits to the ED were avoidable. More and more plans are also downcoding reimbursement based on a list of final diagnosis codes that are deemed to be "non-emergent." Again, this is a direct violation of the PLP since these plans are making the determination automatically using a diagnosis code. Patients don't come to the emergency room with a known diagnosis, only symptoms—it is unlawful to deny or reduce coverage based on the diagnosis. An "emergency" versus a "non-emergency" must be determined on a case-by-case basis based on whether the patient's symptoms and complaints reasonably represented to them as a prudent layperson a potential emergency condition. As emergency physicians, we often ourselves cannot differentiate just based on presenting symptoms when a patient first comes to our ED whether they are experiencing an emergent or non-emergent condition. Many conditions, both minor and life-threatening, share very similar symptoms, and we frequently must do a full work-up and exam, sometimes with additional diagnostic tools, before it becomes clear what the ultimate diagnosis is. In fact, a 2013 peer-reviewed study published in JAMA of over 34,000 ED visits found that for those discharge diagnoses which could be considered primary care—treatable, the chief complaints reported for these visits were identical to those reported for 88.7 percent of all of the studied ED visits, many of which ended up requiring admission to the hospital, triaged at the highest/most urgent level, or went directly to the operating room. As the authors of the JAMA paper note:

"For example, a 65-year-old patient with diabetes may be discharged with the nonemergency diagnosis of gastroesophageal reflux after presenting with a chief complaint of chest pain; however, that patient still required an emergency evaluation to rule out acute coronary syndrome."

The extremely limited concordance between presenting complaints and ED discharge diagnoses in this study demonstrates that using lists of diagnostic categories as a means for making coverage determinations is a flawed and inaccurate practice.

CMS has previously itself reiterated the point that plans cannot use diagnosis codes to deny or reduce coverage of emergency coverage--most recently in the 2016 Medicaid Managed Care Final Rule. In this rule, CMS states

"Regarding the PLP requirements of the BBA of 1997 and the use of approved lists of emergency diagnosis codes, we remind commenters that consistent with our discussion in the 2002 managed care final rule at 67 FR 41028-41031, we prohibit the use of codes (either symptoms or final diagnosis) for denying claims because we believe there is no way a list can capture every scenario that could indicate an emergency medical condition under the BBA provisions...While this standard encompasses clinical emergencies, it also clearly requires managed care plans and states to base coverage decisions for emergency services on the apparent severity of the symptoms at the time of presentation, and to cover examinations when the presenting symptoms are of sufficient severity to constitute an emergency medical condition in the judgment of a prudent layperson...The purpose of this rule is to ensure that enrollees have unfettered access to health care for emergency medical conditions and that

¹ Doctor-Patient Rights Project (DPRP), "Access Denied Part Two: How Insurance Coverage Denials Can Block Access to Preventive and Emergency Care," 27 November, 2018, available at: https://doctorpatientrightsproject.org/wp-content/uploads/2018/11/Marathon_DPRP_Access-Denied-2_NOV2018_FINAL.pdf.

² Raven MC, Lowe RA, Maselli J, Hsia RY. Comparison of Presenting Complaint vs Discharge Diagnosis for Identifying "Nonemergency" Emergency Department Visits. JAMA. 2013;309(11):1145-1153. doi:10.1001/jama.2013.1948.

providers of emergency services receive payment for those claims meeting that definition without having to navigate through unreasonable administrative burdens." ³

We therefore call on CMS to reiterate the Prudent Layperson Standard in the Final Notice, and affirm with language similar to the above how it applies to coverage of ED visits by QHPs, as required by the Affordable Care Act.

Once again, we appreciate your focus on improving price transparency for the benefit of our patients. Please find our comments on the specific concepts raised in the NBPP below.

Interoperability

CMS is exploring ways to increase the interoperability of patient-mediated health care data across health care programs, including in coverage purchased through the Exchanges. Given the importance of this issue, CMS expects to provide further information and an opportunity for public input in the near future. As CMS considers different policy options, ACEP would like to reiterate our strong support for eliminating all barriers that impede our ability to receive information about our patients and provide the best possible care. As emergency physicians, it is challenging for us to provide comprehensive care to patients who arrive in our ED without a medical record that we can easily access. In many cases, we see patients with acute conditions who we have never seen before. We deal with life and death situations and, with limited information, we must make near-instantaneous critical decisions about how to treat our patients. Therefore, we are particularly anxious to work with hospitals and insurers toward the goal of interoperable electronic health records (EHRs) that will open the door to more comprehensive patient information sharing across sites of care. Linking disparate EHRs will allow us to make more informed decisions and will significantly enhance timely communication with patients, community physicians, and other caregivers. To that end, we support future policies that promote our ability to receive and exchange information about our patients.

Disclosing Costs to Consumers

In the NPBB, CMS includes the following statement:

"...we are interested in ways to improve consumers' access to information about health care costs. We believe that consumers would benefit from a greater understanding of what their potential out-of-pocket costs would be for various services, based on which QHP they are enrolled in and which provider they see. We believe that such a policy would promote consumers' ability to shop for covered services, and to play a more active role in their health care. In particular, we are aware that it can be difficult for consumers to anticipate their financial responsibility when a QHP applies coinsurance, because consumers are largely unaware of the negotiated rate until they receive an explanation of benefits document after the provider renders the service. We are considering different options for disclosure of cost-sharing information, recognizing that cost is a significant factor in creating greater value in health care delivery. For example, we are considering whether to require issuers to disclose a consumer's anticipated costs for particular services upon request within a certain timeframe, or whether to require issuers to disclose anticipated costs for a set number of common coverage scenarios, similar to what they must currently disclose in the Summary of Benefits and Coverage (SBC)." ⁴

³ Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability Final Rule, 81 Fed. Reg. 27749 (May 6, 2016).

⁴ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020 Proposed Rule, 84 Fed. Reg. 229-230 (January 24, 2019).

ACEP agrees that insurers should provide information to consumers about the potential costs of seeking care under their particular coverage. Providers can participate by helping patients interpret their cost-sharing responsibilities (of note not during the emergency but rather at a non-emergent time such as upon purchase of a policy), but the onus should be on insurers to make these costs transparent to patients. We believe that patients today truly do not understand their "high deductible" health plans and there is a dearth of information on "coinsurance," "deductibles," and "co-pays."

While providers and hospitals may be able to provide raw pricing information upfront to patients, without accompanying information from insurers concerning the manner and methodology the insurer has utilized to adjudicate the patient's benefits; little can be achieved in the form of true transparency. This information from insurers is an essential component of transparency. Further, knowing that an insurer paid a member benefit 'at the usual and customary benefit level consistent with the member/patient's plan benefits' is not acceptable. Rather, the insurer must define in specific terms and plain English the manner and methodology utilized by the insurer to adjudicate the patient's plan benefits, notwithstanding an assertion by the insurer that the information is proprietary or confidential—which, more often than not, is an all too frequent insurer response. This often provides the patient with a cryptic response and a limited understanding of what they're ultimately responsible for. Therefore, placing this responsibility exclusively on the shoulders of the hospital, physician, or patient is unfair and of little use in satisfying the objective of CMS' present request for true transparency.

With respect to acute unscheduled emergency care, patients have the right to know from their insurers in advance if the physician treating them is in-network and, as required by the Affordable Care Act, should pay the same cost-sharing if they receive care from an out-of-network clinician that they would have paid to an innetwork physician. Insurers must meet appropriate network adequacy standards that include adequate patient access to care, including access to hospital-based physician specialties.

Regulatory Barriers

CMS is seeking comments on "whether there are any existing regulatory barriers that stand in the way of privately led efforts at pricing transparency, and ways that we can facilitate or support increased private innovation in pricing transparency." While ACEP cannot think of any specific regulatory barriers, we do have some suggestions of actions private plans can take to increase transparency. First, we believe that insurers should more clearly convey beneficiary plan details, such as printing the deductible on each insurance card. This can help patients understand the limits of their insurance coverage and reduce the surprise when they later get a bill. Second, as stated above, insurers should explain a patient's rights related to emergency care in plain, easy-to-understand clear language. Finally, insurance companies should release or make public their contracted, innetwork rates for individual procedures or services, or even their out-of-network coverage rates. That way, consumers can compare costs and have a better understanding of their true out of pocket costs. The lack of transparency around in-network and out-of-network rates for services is alarming, and ACEP has pushed for years for this to be improved.

⁵ 84 Fed. Reg. 230.

Essential Health Benefit (EHB) Packages

In the NBPP, CMS reiterates some of the final EHB policies from the 2019 Payment Notice. CMS had finalized the following options for states to select new EHB-benchmark plans starting with the 2020 benefit year:

- 1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year;
- 2) Replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017 plan year; or
- 3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark.

Although these changes are now final, ACEP continues to strongly oppose them. Each state has its own unique market conditions, and the Affordable Care Act's benchmark plan provisions have ensured that states can have a package of essential health benefits suited to its needs, while ensuring a floor of minimum coverage requirements. As a result of this additional flexibility now granted to states, the items and services covered within a category can vary significantly from state to state. Allowing a state to use the EHB-benchmark plan of any other state, and even allowing the mixing and matching of a particular category or categories and the benefits included within them from different states' benchmark plans, will quickly result in a race towards the bottom of states picking and choosing amongst the skimpiest offerings to design their own minimal coverage standard. States will be able to circumvent state benefit mandates and consumers can be left with a narrow set of benefits that do not ensure them access to the items and services they need to manage their health conditions. This will leave them paying even more out of pocket. Since these final changes could limit access to services and drive up costs for consumers, CMS should carefully monitor how states are modifying their EHB-benchmark plans and be prepared to revert back to the stronger requirements.

In this year's NBPP, CMS also moved up the EHB-benchmark plan submission deadlines for both the 2021 and 2022 plan years to May 6, 2019 and May 8, 2020, respectively. Given the amount of flexibility states now have in setting their EHB-benchmark plans, ACEP urges CMS to require states to provide a significant amount of time for the public to comment on any changes that states are planning to make to their plans.

Medication Assisted Treatment (MAT)

In the NPBB, CMS encourages "issuers to take every opportunity to address opioid use disorder, including increasing access to MAT and normalizing its use." Like CMS, ACEP believes that Medicare beneficiaries should have appropriate access to MAT. Emergency physicians have seen great results with initiating treatment (e.g., buprenorphine) in the ED and starting patients on the path to recovery. By implementing this treatment regimen, we can address a substance abuse disorder (SUD) patient's immediate symptoms and cravings, which allows time to coordinate care and provide a "warm handoff" to substance use disorder specialists and other community resources who can appropriately carry out long-term treatment. There are study results showing promise for ED-initiated buprenorphine and its effectiveness in treating opioid use disorder.

Initiating MAT in the ED has shown to be more successful than simple referral – after one month, 78 percent of patients started on MAT in the ED remained in treatment programs, compared to 37 percent who only

^{6 84} Fed. Reg. 285.

received a simple referral.⁷ Furthermore, studies of patients in California and elsewhere with opioid addiction have demonstrated an instantaneous reduction in mortality after buprenorphine-assisted detoxification, justifying its use in the ED even when access to long-term maintenance and follow-up is not available.⁸ Finally, a study conducted using a retrospective chart review of 158 patients treated at a single ED with buprenorphine for opioid withdrawal found no instances of precipitated opioid withdrawal (a potential medical complication of buprenorphine), and a greater than 50 percent reduction (17 percent versus 8 percent) in return-rate to the same ED for a drug-related visit within one month, compared to the return-visit rate for usual care.⁹ In all, research suggests that the sooner we can start patients on the right path and keep them engaged in treatment, the more successful their recovery can be.

Since MAT has proven to be an extremely effective form of treatment, especially in the ED, going forward CMS should consider requiring issuers to cover MAT, rather than simply encouraging it.

State Relief and Empowerment Waivers

ACEP would like to reiterate our previous comments on the recent guidance and concepts related to State Relief and Empowerment Waivers. ACEP strongly believes that this guidance and concepts will create more instability in the market and make it more difficult for vulnerable populations to access care. We have significant concerns with CMS promoting Association Health Plans and short-term, limited-duration plans as viable alternatives to Affordable Care Act Exchange plans. Expanding the availability of these plans will lead to an exodus of healthy people from the healthcare marketplace, thereby distorting the market's risk pool. Such a shock to the market could cause plans in the market to increase premiums, provide less generous benefit packages, or leave the market altogether. Thus, some people who remain in comprehensive plans could also eventually have trouble accessing preventive and other types of services that would prevent them from having to make unavoidable visits to the ED.

Furthermore, both Association Health Plans and short-term, limited-duration plans are not required to cover all ten EHBs. We believe that it is critically important for all insurance plans to cover all ten EHBs. Without such guaranteed coverage, consumers can be left with a narrow set of benefits that do not ensure access to the items and services they need to manage their health conditions. Consumers who purchase less comprehensive health plans may wind up deferring more routine care or visiting a primary care physician or specialist for more minor conditions or symptoms. Such deferral or delay will often result in their condition or symptoms becoming exacerbated and eventually, result in a trip to the ED. At this point, due to the progression of their condition, their care in the ED will be much costlier and more complex than if they had earlier access to more routine care in a physician's office.

Therefore, again, we ask that the Trump Administration rescind both the guidance and the concepts immediately.

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⁷ D'Onofrio G, O'Connor PG, Pantalon MV, et al. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. JAMA. 2015;313(16):1636-1644.

⁸ Elizabeth Evans et al., "Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006-10," Addiction 110, no. 6 (June 2015): 996-1005.

⁹ Berg ML, Idrees U, Ding R, Nesbit SA, Liang HK, McCarthy ML. Evaluation of the use of buprenorphine for opioid withdrawal in an Emergency Department. Drug Alcohol Depend. 2007; 86:239-244.

¹⁰ ACEP's comments can be found at: https://www.acep.org/globalassets/new-pdfs/advocacy/acep-comments-on-state-relief-and-empowerment-waiver-guidance.pdf.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

Vidor E. Friedman, MD, FACEP

ACEP President