



Charles N. Kahn III
President & CEO

July 16, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

***RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Vol. 83, No. 95),
May 16, 2018***

Dear Secretary Azar:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to provide comments to the Department of Health and Human Services (HHS) about the referenced Request for Information (Blueprint) on the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Vol. 83, No. 95), May 16, 2018.

We appreciate HHS's interest in finding ways to improve the affordability of prescription drugs and agree that urgent action is necessary. The rising cost of pharmaceuticals is an issue that hospitals are working to manage on a daily basis as evidenced by the study the FAH published with the American Hospital Association (AHA) in late 2016.¹ According to the study, average annual inpatient drug spending increased by 23.4 percent between FY 2013 and FY 2015 and 38.7 percent on a per admission basis over the same time period. Such increases are unsustainable for our patients and hospitals, and we appreciate the opportunity to work with you

¹ Trends in Hospital Inpatient Drug Costs: Issues and Challenges, October 2016,
<https://www.aha.org/system/files/2018-01/aha-fah-rx-report.pdf>

to address this urgent problem. To that end, we offer our comments on a number of the items presented in the Blueprint for comment:

A. Increasing Competition

Distribution Restrictions

The Food and Drug Administration (FDA) uses the Risk Evaluation and Mitigation Strategy (REMS) program to ensure that the benefits of a drug outweigh its risks. Unfortunately, as described in the Blueprint, drug manufacturers often engage in abusive, anti-competitive behaviors that use REMS to block generic drug companies from obtaining samples of brand drugs, effectively preventing them from pursuing the research needed to bring less expensive generic drugs to market. The FAH appreciates steps that have already been taken to use administrative action to help curb these abuses. However, we believe more can be done and welcome further actions to address anti-competitive abuses of REMS. HHS should assess whether existing REMS programs inappropriately restrict access to samples necessary for testing by generic drug makers. Lifting any inappropriate and anti-competitive restrictions in sample access will better enable generic drug makers to develop products that can inject competition into the marketplace and bring drug prices down for consumers and taxpayers.

B. Better Negotiation

Improving Transparency in Prescription Drug Pricing in Medicare, Medicaid, and other Forms of Health Coverage

The FAH agrees with HHS that improving transparency in prescription drug pricing is a critical component to making prescription drugs more affordable for consumers. We appreciate the policies in the Blueprint that promote improved drug pricing transparency. For example, frequently updating and increasing the amount of information on the Medicare and Medicaid Dashboards will meaningfully improve drug pricing transparency and better inform patients of the true costs of treatment options available to them.

Furthermore, the FAH believes there are additional actions that HHS could adopt to improve transparency including requiring drug makers to release details of a drug's unit price, cost of treatment, and projection of federal spending before FDA approval; require drug companies to annually report increases in their drugs' list prices; and produce an annual report on overall prescription drug spending trends.

Value-Based Arrangements and Price Reporting

We appreciate the Department's interest in exploring value-based payment arrangements for prescription drugs. The FAH believes that improving quality, retaining and improving access, and addressing cost for patients should be at the core of any innovation HHS seeks to implement.

As HHS considers how to implement such arrangements, the FAH reiterates its strong belief that such arrangements implemented using the Center for Medicare and Medicaid Innovation's (CMMI) authority must be implemented on a voluntary basis. The FAH has repeatedly expressed significant legal and policy concerns over any proposal to implement a CMMI model under which provider and supplier participation would be mandatory. We believe that CMS has incorrectly interpreted that it may require mandatory participation of providers in a CMMI demonstration. The FAH disagrees that §1115A of the Social Security Act (SSA) provides CMS with the authority to mandate provider and supplier participation in CMMI models. Such mandatory provider and supplier participation runs counter to both the letter and spirit of the law that established the CMMI, as well as the scope of its authority to test models under section 1115A and make recommendations to Congress for permanent or mandatory changes to the Medicare program.

Part B to Part D

HHS requested that stakeholders identify drugs or classes of drugs that would be good candidates for moving from Part B to Part D. ***The FAH opposes the move of any non-self-administered drugs provided in the hospital outpatient setting from Medicare Part B to Medicare Part D in light of patient safety and access risks, the risk of increased Part D premiums, and beneficiary financial burdens, and administrative and operational burdens.*** At present, whether a drug administered in the hospital outpatient setting is covered under Medicare Part B or Part D is determined based on how the drug is typically administered. Drugs that are self-administered by more than 50 percent of patients are considered to be "usually self-administered" and are generally not eligible for coverage under Medicare Part B. The Medicare Administrative Contractors (MACs) are responsible for applying CMS's guidelines and determining whether a drug is "not usually self-administered" and eligible for Part B coverage. The current scope of Part B drug coverage helps to ensure that patients do not unnecessarily rely on physicians and hospitals to provide drugs that are typically self-administered, while still maintaining appropriate Part B coverage for outpatient drugs.

In the Blueprint, HHS does not suggest that it has concerns with the MACs' application of CMS's coverage policies and guidelines for outpatient drugs. Instead, it appears that HHS is requesting comment on whether Congress should permit CMS to move additional categories of drugs (*i.e.*, certain non-self-administered drugs) from Medicare Part B to Part D. The FAH strongly opposes any such reduction in Medicare Part B coverage for outpatient drugs.

Eliminating Medicare Part B benefits for any drugs that are not usually self-administered would create operational issues and potential financial and safety risks for patients. Hospital pharmacies do not typically contract with Medicare prescription drug plans (or pharmacy benefit managers more generally). As a result, when a physician orders, and pursuant to that order a hospital furnishes a drug that is not covered under Medicare Part B to a hospital outpatient, to the extent the patient is billed directly for that drug by the hospital, the patient is personally liable for those drug charges, but may separately seek payment from his or her Medicare Part D plan. If the drug is not on the Part D plan's formulary, then coverage may be denied and the beneficiary may need to appeal the claim. This process imposes significant burdens and financial risks on the beneficiary. In addition, the hospital bears the risk of non-payment by the beneficiary. At present, these burdens serve the purpose of discouraging patients from using the hospital

outpatient department as a pharmacy for self-administered drugs. Expanding this process to non-self-administered drugs, however, serves no proper purposes and imposes unacceptable costs on patients and hospitals. In addition, it would not be feasible or appropriate to make patients responsible for providing their own drugs—presumably purchased from an in-network retail pharmacy—for administration in the hospital outpatient department. In some cases, this approach is wholly unworkable because the physician will not prescribe any drugs until he or she evaluates the patient during the actual outpatient visit. Even where the drug treatment plan is known in advance, the patient and Part D plan would face the financial risk that, upon evaluation by a physician, the drug is not ultimately administered. For example, a chemotherapy patient may present at his or her infusion appointment with a change of condition (*e.g.*, severe anemia) that makes infusion inappropriate, causing the purchased drug to go unused. Of even greater concern, the hospital pharmacy cannot be assured of the safety and efficacy of a patient-supplied drug. Although a drug may be within its printed expiration date, if the patient has not stored the drug in an environment with the proper temperature, humidity, and light, the drug strength, quality, and purity may be affected. In those circumstances, the patient may not receive an effective or safe dose of the drug due to its premature degradation. Finally, encouraging the provision of drugs by patients may actually promote drug waste. Hospital pharmacies can purchase vial sizes and quantities that are appropriate for their overall utilization, and hospital pharmacists can safely repackage drugs in smaller vials in a sterile environment to minimize drug waste. In contrast, any unused drug in a patient-provided vial would be automatically discarded.

As HHS notes in the Blueprint, approximately 27 percent of Medicare beneficiaries do not have Medicare prescription drug coverage. This coverage situation makes the financial risks of transitioning drugs from Part B to Part D coverage more acute for beneficiaries. Beneficiaries without prescription drug coverage would see their financial responsibility grow as they essentially lose coverage for the physician-administered drugs moved from Part B to Part D. Depending on the categories of drugs involved, such a policy could erode coverage under Original Medicare for certain conditions that require physician-administered drugs (*e.g.*, cancer care). Furthermore, the 27 percent figure may underestimate the number of beneficiaries that would not have Part D coverage under this policy. Because rising Part D costs would likely produce premium increases, under this policy, a larger share of Medicare beneficiaries may decline Part D coverage. When these beneficiaries are treated at the hospital outpatient department, they will face personal financial liability for the drug costs no longer covered under Part B, and the hospital would ultimately risk non-payment for some or all of the drug charges.

Lastly, the FAH urges HHS to address key issues with Medicare Part D costs before exploring further burdening Part D plans. HHS's Blueprint indicates that Medicare Part D reform is needed and presents a number of potential avenues for improving Medicare Part D. Expanding Medicare Part D by moving coverage for certain non-self-administered drugs from Part B to Part D would overburden a Medicare Part D program that is currently unable to efficiently provide cost-effective coverage for self-administered drugs. Therefore, at a minimum, the exploration of any additional coverage that might be taken on by Part D plans would be premature at this time.

Site Neutrality for Physician Administered Drugs

In the Blueprint, HHS observed that facility fees for physician-administered drugs are different between hospital outpatient departments and physician offices and requested comments concerning the effects of a site neutral payment policy for physician-administered drugs. The FAH opposes site neutral payment for drug administration procedures because it is inappropriate and unworkable, is inconsistent with the principles of a prospective payment system, and would negatively impact patient access and quality of care.

Hospital outpatient departments, unlike physician offices, must meet health and safety regulations—Conditions of Participation—that do not apply to physician offices. These requirements impose higher infrastructure costs on hospitals as compared to physician offices providing the same services. Additionally, a raw comparison of facility fees for physician-administered drugs in these two settings is misleading because the reimbursement systems used for outpatient hospital services and physician office services are fundamentally different. Under Medicare Part B, hospitals are generally reimbursed for outpatient facility fees pursuant to the Outpatient Prospective Payment System (OPPS) while physician offices are paid in accordance with the Medicare Physician Fee Schedule (MPFS). Ultimately, differences between the OPPS and MPFS rates for drug administration services turn on the prospective nature of the OPPS and differences in the resource costs for those services in the hospital outpatient and physician office settings.

Unlike a per-service fee schedule that pays separately for each properly coded service (like the MPFS), the OPPS operates as a prospective payment system. For example, under the OPPS, when level 1 or level 2 drug administration services are performed with another separately payable service, they are packaged with that service and are not separately paid. When adopting this packaging rule last year, CMS reiterated that appropriate packaging “is an inherent principle of a prospective payment system.” 82 Fed. Reg. 52356, 52395 (Nov. 13, 2017). “The OPPS, like other prospective payment systems, relies on the concept of averaging, where the payment may be more or less than the estimated costs of providing a service or package of services for a particular patient, but with the exception of outlier cases, is adequate to ensure access to appropriate care. Packaging and bundling payments for multiple interrelated services into a single payment creates incentives for providers to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment.” *Id.* These packaging rules—which are integral to the OPPS but not to the MPFS—mean that any comparison between hospital outpatient and physician office facility fees is not an apples-to-apples comparison.

Differences between the amounts paid under the OPPS and the MPFS for drug administration services are also driven by cost differences between the hospital outpatient and physician clinic settings. The resource-based relative value scale (RBRVS) underlying the MPFS is based on the resource costs of a service in the physician office setting. Meanwhile, each ambulatory procedure code (APC) used for OPPS reimbursement is weighted based on the hospital outpatient resource requirements of the service. Thus, differences between OPPS and MPFS facility fees for drug administration services reflect the differing resource costs of these services in these settings. In some cases, the resource costs differ because the purpose of the administration may be different in the two settings, or the acuity and complexity of typical cases

differ. In addition, some functions that are typically taken on by nurses in physician offices are typically handled (at higher cost) by pharmacists and pharmacy technicians in the hospital setting. For example, a physician's office may rely on registered nurses to mix chemotherapy drugs, while a hospital outpatient department incurs the higher costs of having a pharmacist and pharmacy technician prepare chemotherapy drugs. These potentially higher costs are warranted, however, as hospitals are better positioned than the typical physician office to ensure the delivery of high quality care and to protect patient safety when dangerous drugs are involved. Certainly, there may be individual cases where, due to the prospective nature of the OPSS, the OPSS payment may be more than the estimated cost of providing a package of services to an individual patient, but there are also cases where the OPSS payment is less than the estimated cost. Ultimately, reimbursement rates in these two settings properly reflect differences in costs between the between hospital outpatient departments and physician offices administering the drugs.

Because cost differences and packaging drive the relative difference between OPSS and MPFS reimbursement for drug administration services, adopting a site-neutral payment policy for drug administration services would result in the payment for hospital outpatient encounters involving drug administrations falling below the hospital's typical estimated costs. Such a change might make the operation of certain hospital outpatient departments—particularly ambulatory infusion departments—financially non-viable, reducing patient access to care.

The FAH also believes that the hospital outpatient environment is the most appropriate setting for certain drug administration services, including chemotherapy services. As we noted, hospitals are better positioned than the typical physician office to ensure the delivery of high quality care and to ensure patient safety when dangerous drugs are involved. The hospital pharmacy is under the direction of a pharmacist, whose professional training focuses on drug handling and safety. In the context of chemotherapy drugs, the oversight of a pharmacist can better guard against a host of drug errors, from dosages that are too high or too low (e.g., due to errors in diluting the drug or the failure to accurately adjust the dose based on a patient's body surface area), the use of drugs that are no longer effective (e.g., due to improper storage or handling), and the administration of contaminated/non-sterile drugs (e.g., due to mishandling of drugs or failure to maintain the hood).

Site Neutrality Between Inpatient and Outpatient Settings

HHS also requested comments on the differences in Medicare payment rules for drugs in the inpatient (Part A) and outpatient (Part B) settings. The FAH is concerned that extremely high-cost drugs may overburden the Inpatient Prospective Payment System (IPPS) and appreciates HHS' attention to Medicare drug payment rules in the inpatient setting. As the FAH observed in its comments on the FY 2019 IPPS Proposed Rule, the IPPS is not well suited for providing coverage for extremely high costs drugs. By way of example, chimeric antigen receptor (CAR) T-cell therapy involves a very high cost drug product (in excess of \$350,000). Under current law, absent a new technology add-on payment, revenue neutrality rules would result in the underpayment of CAR T-cell therapy, the reduction of IPPS payments for core hospital services, and further increases to the fixed-loss threshold for outlier payments. In addition, the IPPS Medicare Severity Diagnostic Related Group (MS-DRG) system would result in hospital payments substantially varying with labor costs despite labor costs being insignificant

in light of the six-figure price-tag for the CAR-T cell therapy drug product. In the near-term, the FAH has recommended that CMS create a new add-on payment methodology for CAR T-cell therapy that is based on the blended average sales price (ASP) of the drug product, providing Congress with the opportunity to create a long-term solution. The use of a blended ASP would incentivize price-based competition between CAR T-cell drug manufacturers, while ensuring that patients have access to this potentially life-saving therapy and that hospitals are reasonably compensated for drug costs they cannot control.

CAR T-cell therapy presents an extreme example of how the IPPS is not well adapted to coverage of very high cost drugs. Incorporating very high-cost drugs into the weighting of MS-DRGs will depress payment rates for other services while underpaying for the very high-cost drugs. The FAH, therefore, urges this Administration to work with Congress on a more sustainable solution to reimbursement for very high-cost drugs that are no longer eligible for new technology add-on payments.

As a more general matter, however, fundamental differences in the IPPS and OPSS warrant disparate payment for more typical drugs. IPPS payment amounts are calculated on a per-discharge basis, and vary based on the beneficiary's MS-DRG assignment, geographic factors, and some additional amounts (e.g., the hospital value based payment amount). No separate payment is made for drugs in the inpatient setting, unless a new technology add-on payment applies. The relative weights of MS-DRGs are based on the average resources required to care for patients in each MS-DRG, taking typical drug costs into account. In contrast, OPSS payment amounts are calculated based on the actual procedures furnished, with various APCs being conditionally or unconditionally packaged. For separately payable drugs, the hospital also generally receives separate payment for Part B covered drugs based on the ASP of the drug, plus 6 percent, reflecting both the typical purchase price of the drug and the associated overhead costs. In typical cases, the inclusion of drug costs when establishing the relative weights of MS-DRGs for IPPS purposes is sensible because the larger array of resources involved in inpatient care ensures that drug costs are not the dominant force in weighting MS-DRGs. In contrast, if drug costs were included in the weighting of APCs instead of being separately reimbursed under an ASP plus 6 percent formula, hospitals would be drastically underpaid or overpaid for outpatient services based on the actual drugs administered during an outpatient encounter.

Lastly, the FAH emphasizes, that the determination as to whether a patient should be treated in the inpatient or outpatient setting is and should be based on the physician's professional determination, guided by medical necessity considerations. In fact, CMS's longstanding policy recognizes that physicians determine whether and when to admit a patient to or discharge a patient from inpatient care. Because the determination of when to admit patients lies with physicians, and not with hospitals, it would be fundamentally unfair to reduce hospitals' payments given hospitals' limited involvement with that determination. The FAH would oppose a policy that second guesses physician admission orders based on drug pricing and urges CMS against exploring any such approach.

C. Create Incentives to Lower List Prices

Reducing the Impact of Rebates

The Blueprint notes that Pharmacy Benefit Managers (PBMs) assist buyers (such as insurers and large employers) to procure lower drug prices and help sellers (drug manufacturers) pay rebates to secure placement on health plan formularies. The Blueprint further notes that most current PBM contracts allow them to retain a percentage of the rebate collected and other administrative or service fees. However, the Blueprint questions whether PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher fees) rather than lower prices and may signal what HHS considers a PBM conflict of interest with their customers. It is not clear what authority HHS has or would employ to regulate PBMs and how it would do so, but to the extent the Department is considering making any changes to the Anti-Kickback Statute (AKS) discount safe harbor and the group purchasing (GPO) safe harbor, the FAH urges the Department to proceed carefully to avoid unintended consequences.

The discount and GPO harbors at 42 C.F.R. §§1001.952(h) and (j) are important tools that allow hospitals and other providers and suppliers to receive lower prices on goods and services while ensuring that legitimate arrangements do not pose any risk under the AKS. The discount safe harbor applies to price discount and rebate arrangements between purchasing hospitals and providers and their suppliers (typically, a manufacturer or distributor). The GPO safe harbor, meanwhile, applies to the arrangement between the GPOs, hospitals and other providers, and suppliers. It is important to recognize that, whereas the Department's Office of Inspector General (OIG) has published these safe harbors, the statute contains exceptions to the AKS for discounts and for GPOs. *See* sections 1128B(b)(3)(A), (C) of the Social Security Act. Congress did not give the Secretary the authority to narrow the statutory exceptions through regulatory safe harbors, and courts have found that regulated parties may rely on either a statutory exception *or* a corresponding regulatory safe harbor. Indeed, there is a long line of precedent that administrative agencies have no authority to interpret criminal statutes.

It is unclear from the Blueprint how any potential changes to the discount and/or GPO safe harbor would impact our member hospitals, and therefore it is difficult to offer thoughtful and thorough comments at this time. However, we caution that HHS should consider that various stakeholders across the health care supply chain, not simply PBMs, rely on these safe harbors to provide legal certainty for certain business arrangements that achieve lower costs for providers and Medicare beneficiaries. Virtually all of the country's hospitals use at least one GPO, and on average, hospitals belong to 2-4 GPOs, which compete with one another for hospital business². According to the same data, GPOs reduce healthcare costs by up to \$55 billion annually and save each hospital an average of 10 percent to 18 percent compared to direct purchases. As such, we encourage the Administration to consider the impact any suggested changes may have on the health care supply chain, generally.

² Healthcare Supply Chain Association, <https://www.supplychainassociation.org/about-us/faq/>

Thank you for the opportunity to comment on these important issues. Please do not hesitate to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Shirley M. [unclear]". The signature is fluid and cursive, with a large initial 'S' and a distinct 'M'.