American Hospital Association™
Advancing Health in America

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Brenda Destro
Deputy Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Office of Science and Data Policy
Attn: EPAEDEA

RE: Request for Information: Ensuring Patient Access and Effective Drug Enforcement

Dear Dr. Destro:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide feedback on the Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Planning and Evaluation's request for information on ensuring patient access and effective drug enforcement regarding controlled substances. Every day, our members witness the devastating effects of substance use on their communities. We are committed to helping end this crisis while ensuring that patients can continue to access needed and appropriate therapies.

The AHA has been helping our members balance responsible opioid stewardship with effective patient care for several years. We have worked closely with our members, community partners and federal partners to identify and promulgate evidence-based policy and clinical opportunities and strategies. We are eager to share these ideas as well as support their continued evaluation and implementation. We have expressed some of these ideas to various federal partners before, and some of them are new ideas that we have gathered through member outreach.

OBSTACLES TO LEGITIMATE PATIENT ACCESS TO CONTROLLED SUBSTANCES

DEA Quotas for Production of Opioid Medications. In the past few years, the Drug Enforcement Administration (DEA) has proposed to implement limits on the amount of opioid medications that a single manufacturer may produce in a given time period. We concur with DEA that setting quotas for the production of opioid medications – and thus limiting the amount of substances available – can be an effective step in "preventing the accumulation of controlled substances in amounts exceeding legitimate need," and therefore reduce the chances that these powerful medications will be diverted for non-medical illicit purposes. However, opioids are commonly administered in hospitals to relieve the pain of significant trauma, surgery, cancer that has metastasized to the bone or invaded the brain, severe burns and other significant diseases or disorders. Thus, we believe that in its intense focus on diversion, DEA is missing another critical challenge: ensuring enough medication to fulfill legitimate and critical medical needs.

As DEA is well aware, hospitals and health systems continue to experience critical shortages of a number of injectable opioid medications – such as morphine, hydromorphone and fentanyl – due to both a slowdown in production and a component problem at a major manufacturing facility. These intravenous (IV) opioids are widely used and essential to appropriate patient care in hospitals and in other practice settings for the treatment of acute and chronic pain and for sedation purposes. Beyond the negative impact on patient care, inadequate supplies of these drugs also create burdensome and potentially dangerous workarounds for health care staff who must use alternative, often suboptimal, products. Another consequence of shortages has been higher drug prices.

To ensure that legitimate medical needs are met, it is essential that drug shortages be explicitly considered in setting and adjusting aggregate production quotas (APQ) and that resolving shortages be deemed as a relevant factor considered in the procedures for applying for and fixing individual manufacturing quotas. Proactively considering shortages will safeguard patient health and safety and ensure critical needs are met.

Furthermore, we recommend that DEA routinely consult with the Food and Drug Administration's (FDA) drug shortage staff, who collect and publish relevant data on all national drug shortages, when establishing and adjusting quotas. Obtaining such shortage data from FDA will help ensure that DEA's annual APQs are set to provide "adequate supplies for the United States' legitimate needs." FDA can produce shortage data broken down by dosage form (such as injectable versus oral forms), providing more granular data about the actual supply and availability of medications used by hospitals and health systems. This may provide a clearer picture of diversion risk, as IV opioids dispensed in clinical settings are tightly controlled and thus pose a far lower risk of diversion than other oral dosage forms dispensed directly to patients.

Limits and Restrictions on Prescriptions. In addition to shortages in supply, well-intentioned restrictions on the amount of a controlled substance that clinicians may prescribe at one time can result in patients who legitimately need controlled substances to manage pain being unable to access treatments. Each state has different rules: some require a new paper prescription every 30 days; some prohibit faxed prescriptions; and many plans require prior authorization before prescriptions are filled.

In concept, we acknowledge that some limits and restrictions have merit. When fills are larger than necessary, patients can prolong their exposure to controlled substances, which increases their susceptibility to addiction. Even if patients decide they no longer need the medication, most are unaware of proper disposal and thus medication is accessible to those who do not need it. However, any limits on prescriptions should be based on evidence. Arbitrarily limiting prescriptions to three days or with no refills without considering the patient's condition, as many states have attempted to do, significantly limits legitimate access to these medications. Even when refills are permitted, consider the hardship of a patient in intense pain who must somehow make it to the pharmacy multiple times a week to find relief, or the low-income patient who incurs a new copay for every new prescription.

Thus, the AHA recommends that HHS and its partners work with researchers and our members to develop prescribing guidelines based on patient characteristics, including diagnosis. Many of our members already have created internal guidelines using data-driven observations of how much of a controlled substance a patient reports to have needed based on his or her diagnosis or procedure. The Centers for Medicare & Medicaid Services (CMS) could promulgate these guidelines in its own programs and encourage commercial payers to do so as well. Similarly, CMS could lead the way by thoughtfully amending the type and manner of medications covered to improve access for patients who legitimately need to use controlled substances; for example, covering daily dosing programs.

Fear to Prescribe and Fill. In addition to the logistical barriers between patients and legitimate controlled substances, clinicians have reported unease or even outright fear in prescribing and filling orders for controlled substances. They perceive that DEA is constantly monitoring their activities and fear that any misstep, such as medications being diverted for unintended use, will result in massive penalties. This concern is particularly strong when patients are discharged to the community, and inpatient prescribers are even more uncomfortable prescribing opioids because patients' medications are no longer under the tight control maintained in the inpatient setting. Pharmacies, too, feel that in some cases it is easier to simply refuse to dispense controlled substances than to risk one's reputation and practice. The vast majority of clinicians appropriately prescribing controlled substances to individuals in severe pain deserve the public's trust and should not be subject to a never-ending loop of litigation

that does not help those harmed. We recognize that it is difficult to differentiate the well-meaning prescribers from the few unscrupulous individuals who have chosen to become involved in the illegal diversion of medications to other uses; we believe that shifts in law enforcement tactics and surveillance to focus on collaboration rather than punishment would help assuage prescribers' fears and allow them to best prescribe the medications needed.

DIVERSION OF CONTROLLED SUBSTANCES

Controlled substances are diverted from legitimate use for reasons larger than policy can address directly, including addiction and social and economic pressures. While our members work with their communities to address these more entrenched issues, there are barriers that the federal government can address to limit the immediate harm caused by diversion. Below, we discuss major barriers to prevent diversion as well as a potential solution.

Barriers to Collaboration across Providers, States and Law Enforcement. Many facilities and prescribers who operate near state borders report that diversion most often occurs when neighboring states have inadequate monitoring systems; without timely information sharing across borders, even states with robust surveillance in place are limited in how they can prevent diversion when individuals can simply drive across state lines. Because of the interstate nature of these crimes, individual state licensing boards frequently claim that they do not have jurisdiction to take action. Reporting diversion to DEA and the Department of Justice (DOJ) is an arduous and time-intensive process; a lack of enforcement allows diversion to continue and grow. In addition to a lack of collaboration between and among states, hospitals and health systems rarely get sufficient feedback from law enforcement on diversion prevention activities.

Limits to Insurance Oversight. Many AHA members have reported that individuals procuring controlled substances for illegitimate use pay cash (as opposed to billing insurance), which negates any oversight strategies – like prior authorization or refill limitations – the insurance company may employ.

Support for State Drug Courts. These specialized docket programs target criminal defendants and offenders (including juveniles) who have alcohol and other substance dependency issues. The courts offer individuals the opportunity to enter treatment programs under court supervision in lieu of a jail sentence. Decriminalizing addiction provides access to these intensive programs so low-level offenders can focus on long-term recovery instead of punishment and potentially recidivism. Under DOJ, the Bureau of Justice Assistance and the National Institute of Justice recognize that drug courts can be an effective solution to addressing underlying causes of diversion and provide evidence-based resources on drug court programming.

The AHA believes that DOJ and DEA should support the further development of drug courts at the state level by: 1) examining how drug courts can run efficiently and effectively; 2) establishing a federal expert working group to develop best practices and 3) providing funding. Several AHA members have already partnered with state-run organizations and universities to better manage justice-involved individuals with substance use disorders, but most states need additional support to participate in the drug court system.

COLLABORATION BETWEEN FEDERAL, STATE, LOCAL AND TRIBAL LAW ENFORCEMENT AGENCIES AND THE PHARMACEUTICAL INDUSTRY

In addition to the collaboration between law enforcement and states mentioned above, the AHA believes that a dedicated office to liaise between DEA and the pharmaceutical industry could head off many issues before they grow. DEA could create an Office of Clinical Affairs to help ensure that DEA personnel are available to address the clinical implications of shortages of controlled substances, thereby better balancing the agency's current focus only on diversion control and enforcement. The office also could be dedicated to tracking lot numbers of pharmaceutical shipments to prevent large-scale diversion, and it could focus on how to align regulations across federal and state agencies, including licensure bodies, to endorse efficient and complementary laws.

MEDICAL EDUCATION, TRAINING AND GUIDANCE FOR PAIN MANAGEMENT AND OPIOID PRESCRIBING

Evidence-based guidelines, training and resources on pain management and opioid prescribing exist. Many organizations, including our members and the Centers for Disease Control and Prevention (CDC), have promoted these resources and made them easily available. However, gaps remain due to limited incentives to use those resources as well as a lack of guidance on how to operationalize prescribing recommendations – that is, how to incorporate guidelines into day-to-day workflows.

Guidelines on Collaboration and Licensure. Pain management should be multifaceted, involving multiple modalities of treatment and types of caregivers. While opioid prescribing guidelines are available, less accessible are resources on encouraging collaboration between and among several caregivers and clinicians. For example, our members have requested clearer guidance on when physician prescribers may collaborate with daily dosing programs or non-hospital opioid treatment programs and what information can be transferred back and forth.

We believe that providers need more information on how and when to work with clinicians and caregivers outside of the hospital and health system to manage a patient's pain. Many questions arise regarding licensure requirements – e.g. which clinicians are allowed to do what, and what levels of training and education are required for which types of services. State medical boards should provide clear conditions for pain management education, prescribing, professional services and information sharing.

Non-opioid Pain Management. Opioids and other controlled substances are powerful drugs used to treat intense pain that can otherwise not be adequately controlled. Scientific evidence points to several types of effective pain management treatments that do not carry the same risks that can be used in complement to or instead of controlled substances. However, these modalities are not always offered to patients in pain. HHS should focus on improved education, training and incentives for using these treatments, including:

More robust education around pain in graduate and continuing medication education. Programs that educate and train clinicians of all kinds – including physicians, dentists, psychologists, occupational and physical therapists, physician assistants, nurses and nurse practitioners – should increase the amount of time spent on the fundamentals of pain. Curricula should address the pathophysiology of pain, pain assessments, types of pain experience, cause-specific treatments and alternatives, and the basics of tending to pain (immobilization, rest, ice, compression and non-steroidal anti-inflammatory drugs – NSAIDs, like ibuprofen and naproxen). Currently, medical education dedicates only a small proportion of the curriculum to managing pain; this amount is disproportionate to the main patient goals following medical procedures (to avoid pain and regain function). Several organizations, including the AHA, the Association of American Medical Colleges, the American College of Emergency Physicians and the American Nurses Association, have already compiled resources and training on these topics; HHS should work with these organizations to highlight and disseminate best practices.

Training in patient communication. There is a major gap between patients' expectations for pain management and reality. It is unreasonable to expect zero pain immediately following a major medical procedure. Clinicians' top goal is to help patients feel better; the fastest way to that goal is a strong medication, but we know that "fastest" is not always equivalent to most effective, sustainable and safe. Because of these factors, clinicians often have a hard time communicating with patients and managing their expectations. Medical education should include specific curricula around clear and simple patient communication, including how to set realistic goals and cope with side effects of medical procedures.

Incentivize training. In order to ensure that pain management is a major part of clinical

education, there have to be incentives to pursue it. In addition to updating educational and licensure requirements, this means that reimbursement from payers, including CMS, should be competitive for specialties and facilities that address pain management and addiction. Federal grants should fund residency positions, as well as education and training programs in underserved areas. Additionally, clinicians may need financial support to keep their medical knowledge up-to-date so they can continue addressing patient needs effectively.

STATE PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS)

CDC calls PDMPs "among the most promising state-level interventions to improve opioid prescribing, inform clinical practice, and protect patients at risk." However, the impact of PDMPs is limited by lack of interoperability across states and, sometimes, poor usability. To improve surveillance on prescriptions from multiple providers by patients, there needs to be a way for states to see PDMP reports and data and communicate in real-time with neighboring regions, since individuals often go "doctor shopping" across state lines. In addition, states would benefit from being able to see outputs from data elements used in PDMPs from government agencies like the Department of Veterans Affairs and CMS.

All states can improve the usability of their PDMPs. Federal guidelines can help highlight best practices and the most important data elements. Our members have suggested several specific improvements:

- Improve the search field's flexibility; search fields are often too "precise," so partial names or incorrect capitalization hampers results.
- Include gabapentin and naloxone in reports, as gabapentin is considered a schedule V drug in some states and has potential for abuse.
- For all chronic pain patients, include indication, ICD-10 diagnosis, what treatments have been tried, pain plan being used, last urinary drug testing result, and future pain management plans.
- Proactively send notifications to physicians when patients get another prescription.
- Include daily dosing programs (start and discharge date, medication) in PDMPs.
- Allow non-physicians (e.g. nurses) who support monitoring to access PDMPs.
- Compile data into a main dashboard to show general comparisons and prescribing patterns for comparable prescribers.
- Incorporate use of PDMPs into retail pharmacy workflow processes so that the system is reviewed before final completion and dispensing of controlled substance prescriptions.

As providers move toward increased use of electronic health records (EHRs), PDMPs should be optimized for integration into these clinical tools, and on a much larger

scale. We understand that upgrading and integrating various data sources into EHRs carries several challenges; thus, we encourage HHS and its partners to investigate the opportunities for PDMP integration into various EHR platforms.

In addition, the AHA and various stakeholders have voiced interest in a “national” PDMP, where sharing of information across state lines is automatic. While such a system merits development, we urge HHS and its federal partners to exercise caution in the deployment of a national information sharing. Our members have raised concerns about the potential for breaches in privacy, over-reach (i.e. use of PDMP data beyond clinical purposes) and use of data for criminal prosecution. HHS and its partners should consider the opportunities and barriers to a national PDMP and work with our members and other stakeholders to develop a long-term plan for secure and effective data sharing.

We thank you for the opportunity to comment on this RFI. Please contact me if you have questions, or feel free to have a member of your team contact Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org.

Sincerely,

/s/

Ashley B. Thompson
Senior Vice President
Public Policy Analysis and Development