AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide input to the U.S. Food and Drug Administration (FDA) on how to best reduce the regulatory burdens faced by physicians. As physicians are facing ever-growing regulatory demands, we appreciate FDA's focus on eliminating those that may serve to limit physician and patient access to critical drug and device products or place additional strain on the workloads of busy practices. Below we have highlighted areas where the AMA believes the FDA could re-evaluate its current policies and potentially limit burdens on physician practices while still ensuring patient safety.

Drug Compounding Draft Guidance: Insanitary Conditions at Compounding Facilities

The physician community has been closely following the FDA's implementation of the Drug Quality and Security Act of 2012 (DQSA). As physicians frequently rely on compounded drug products to provide critical treatments to patients, the physician community is particularly concerned with the agency's 2016 draft guidance, *Insanitary Conditions at Compounding Facilities*.

As a routine part of medical practice, physicians across a number of specialties frequently prepare sterile drug products in their offices for administration to patients. Preparation of sterile drug products for patients can include activities such as drawing up a steroid joint injection or botulinum toxin injection with a local anesthetic, preparing allergy/immunotherapy injections for individual patients, buffering lidocaine, and a number of others. In the majority of cases, these activities are routine practices that physicians have been engaging in for years. In many cases, they represent the standard of care for a particular condition. Physicians across specialties have a long history of preparing sterile drug products that provide safe and effective treatments to patients. There is no compelling body of evidence showing these routine activities, when performed in physician offices, pose any increased risk to patients of infection or other adverse events.

The physician community maintains that the routine preparation of sterile drug products at the point of care for administration to patients is not a drug compounding activity. These activities should not be treated as such and should not be subject to the same oversight and compliance policies as compounding facilities engaged in large volume, high risk manipulations.

The FDA's 2016 draft guidance, *Insanitary Conditions at Compounding Facilities*, included physician offices in the definition of a compounding facility, thus proposing to require physician offices engaging in the routine preparation of sterile drug products to meet the same equipment and facilities requirements as pharmacies. Physicians are already struggling under the weight of significant regulatory burdens from new quality reporting programs, electronic health record requirements, and others. If additional burdensome regulatory requirements involving significant capital expenditures and construction projects are levied on physician practices, most practices will instead choose to procure sterile products elsewhere at much higher costs or stop offering these treatments all together. This will undoubtedly result in additional burdens and significantly higher costs to physicians and patients while doing little to increase the safety profile of the drugs at issue.

While our concerns regarding the potential impacts of FDA's proposal remain, we were pleased to see the Agency signal that it plans to address these issues in new draft guidance to be released in 2018. The AMA hopes to continue working closely with the FDA and other stakeholders, including other physician groups and the United States Pharmacopeia, to reach consensus on an appropriate compliance policy for physicians preparing sterile drug products as part of their clinical practice.

Unique Device Identifier (UDI) Implementation

Widespread implementation and access to the UDI for medical devices will improve post-market surveillance and patient safety. The AMA strongly supports such implementation and use. We were an early proponent of the enabling legislation and the AMA continues to commit significant resources to UDI implementation to ensure patient safety and strong post-market surveillance capabilities will exist in the near future. In support of the foregoing, the new electronic health record (EHR) certification requirements will allow capture and transmission of the full UDI (which includes both the device identifier and the production identifier) and will be implemented throughout 2018. EHRs and clinical registries are the most appropriate and streamlined method to capture and manage the UDI as it will provide physicians and patients ready access to such information over time with relevant clinical information while also supporting near future, scalable access for public health research and sentinel monitoring.

The AMA continues to have concerns that requiring capture of the device identifier on administrative claims does not represent a patient-centered solution and lacks longitudinal consistency and reliability as patients switch health insurers regularly. In addition, it is a duplicative and costly solution that imposes administrative burdens on providers, payers, and patients as the latter do not typically track and store claims data.

We urge the FDA to consider the costly, burdensome, and incomplete nature of mandating the device identifier portion of the UDI on administrative claims forms. Instead, the full UDI should be captured within a patient's EHR and, where applicable, clinical registries. Registries that collect data from EHRs could gather UDI data in the aggregate to support comparative studies and post-market surveillance. For further discussion of the AMA's views on appropriate capture of the UDI, please see the attached letter sent to the Centers for Medicare & Medicaid Services' Administrator, Seema Verma last year.

The AMA appreciates your efforts to examine ways to reduce regulatory burdens that may impact the physician-patient relationship. We look forward to continuing to work with you on these important

issues. If you would like to discuss these recommendations further, please do not hesitate to contact Shannon Curtis, Assistant Director of Federal Affairs, at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD

Attachment