EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

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November 22, 2022

Dr. Robert Califf
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Commissioner Califf,

The HIMSS Electronic Health Record (EHR) Association is a national trade association of EHR developers serving the vast majority of hospital, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs and other health IT across the United States. Together, we work to improve the quality and efficiency of care through the adoption and use of innovative, interoperable, and secure health information technology.

On behalf of our 30 member companies of the EHR Association, we are pleased to provide commentary to inform the Food and Drug Administration's *Revising the National Drug Code Format and Drug Label Barcode Requirements (Docket No. FDA-2021-N-1351)*, that is intended to minimize the impact of FDA running out of ten-digit national drug codes (NDCs) by adopting a single, uniform 12-digit format for FDA-assigned NDCs.

The FDA expertly explained the need for the transition from 10-digit to 12-digit NDC codes, and we are pleased that this issue has been identified in such a way as to avoid a last-minute rush to address it. We believe it will be a straight-forward step when the FDA begins assigning 12-digit NDC codes to new medications five years after the effective date of the final rule, but we do have concerns about the proposed three-year transition period related to the NDC code conversion, as we believe the FDA has not sufficiently considered the implications for stakeholders who are downstream from the drug manufacturers, such as health IT software developers.

As health IT developers, this change will affect numerous workflows relied upon by our clients, including everything from ePrescribing to Prior Authorization to Immunization Registry interfaces. We hope the input in this document can be educational for the FDA as you decide which elements of the proposed rule to finalize and which to amend.

We certainly support the need for a transition period, but we also agree with the FDA that there are potential risks to public health and safety associated with such a long period of adjustment. We believe that the risks to the public outweigh the challenges posed to manufacturers by a requirement to convert their product labels, and we recommend shortening the three-year transition period to a shorter duration.

As stated, we anticipate there could be several challenges during the transition period (three-years as proposed). Our member companies and the industry at large will need to identify a path to support both the old 10-digit NDC codes, 10-digit NDC codes converted to 12-digit NDC codes, and new 12-digit NDC codes issued by the FDA during that transition. This is significant work and potentially highly confusing.

Another challenge arises from the fact that all patient records in the health IT databases of our collective clients include historically recorded medications and medication allergy interaction information. It will be important to determine the best strategy for converting that historical data from 10-digit NDC codes to the new 12-digit NDC code format; the fact that the leading zeroes will need to be added to multiple NDC segments in many cases and not just to the beginning of the codes means this is not straightforward. It will be important for all stakeholders to take a consistent approach here, which will require guidance by the FDA. Any such plan will also need to assess whether there is a way to safely do this in an automated manner or whether it would require review by a clinician (like the ICD-9 to ICD-10 conversion). If the latter, regulators would need to be mindful of the significant burden this would be for healthcare organizations and evaluate what that means for the time required.

Additionally, if there is a medication that was dispensed historically and is recorded in a patient's chart but is no longer manufactured, we interpret that to mean that that 10-digit NDC code must be transitioned to a 12-digit NDC code because there could be drug-drug interaction and/or drug-allergy recorded that remains relevant. We ask that the FDA explicitly address this scenario to verify what approach the industry should take.

It's also important to note that the vast majority of health IT solutions in use today utilize Drug Data Compendia within their medication ordering/management solutions, including Clinical Decision Support triggers for drug-drug and drug-allergy interaction checking. Software developers will be dependent on these compendia for the delivery of solutions that support both the 10-digit and 12-digit NDC codes for existing medications, particularly related to the triggering of these critical alerts. Until the compendia sources update and provide the necessary information, however, we will be unable to complete our own development and deploy to our clients.

Additionally, we suggest that the FDA or other government resource maintain a map of the 10-digit NDC codes to new 12-digit NDC codes that can serve as a "source of truth" for the industry in perpetuity to avoid any possible confusion several years down the road.

Lastly, there are also concerns about how interoperability and the exchange of reliable patient data could be negatively impacted over the three-year transition period. We suggest that the final rule from the FDA require health IT developers to only include the converted 12-digit NDC code and not any historical 10-digit version in interoperable outbound messages beginning on the effective date to minimize the chance of confusion.

The above summarizes our concerns if the FDA decides to go with the 10- to 12-digit proposed update. However, a suggestion the FDA might consider is keeping the 10-digit length in codes, but adding a limited set of alphanumeric characters to the string as put forth by NCPDP in their comments (https://www.regulations.gov/comment/FDA-2021-N-1351-0022). Adding a 5-digit alpha numeric labeler code instead of padding with leading zeros would help the FDA continue with issuing unique NDCs while lessening the potential risk of patient harm. This could also serve as an added benefit because some entities already have the ability to add alpha characters to their NDCs strings, which would then lessen development times for at least some stakeholders.

Thank you for this opportunity to share our experiences and expertise. We appreciate the ongoing collaboration to leverage health IT and bring innovations to support clinicians and the patients they serve.

Sincerely,

Hans J. Buitendijk
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David J. Bucciferro
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***Established in 2004, the Electronic Health Record (EHR) Association is comprised of 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families. The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.***