May 16, 2015

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room. 1061
Rockville, Maryland 20852

[Docket No. FDA-FDA-2014-D-2138-0001]

Re: "Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act."

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on the Food and Drug Administration's withdrawal of a proposed rule and publication of a new proposed rule entitled "Draft Guidance for Industry on Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act." as part of the agency's implementation of §503B of the *Food, Drug and Cosmetic Act.* As FDA considers the implementation of this draft guidance, the International Academy of Compounding Pharmacists (IACP) appreciates the opportunity to share our perspectives and to work with FDA in the future on this very important issue.

IACP is an association representing more than 4,000 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding. Compounding pharmacists work directly with prescribers including physicians, nurse practitioners and veterinarians, to create customized medication solutions for patients and animals whose healthcare needs cannot be met by manufactured medications.

ISSUE: Clarification on Reporting Suspected Drugs

Proposed Guidance Document – Lines 218-225

> *For reporting purposes, an adverse event report should describe the known product attributes (e.g., active ingredient(s), dosage form, strength, color, lot number). If an adverse event involves multiple suspect drug products that are compounded by the same outsourcing facility, the outsourcing facility should submit only one report that notes the drug product considered most suspect by the reporter. If the reporter views each drug product as equally suspect, the outsourcing facility should submit only one report that lists all of the drug products as suspect. In all cases, including those where not all of the drug products were made by the outsourcing facility, the report would include information on all suspect drug products.*

Comments

The requirement appearing on lines 224-225 implies that when an adverse event is assumed to be caused by a suspect drug but cannot be directly determined to be associated with a specific drug, the outsourcing facility should identify and list all other medications to which the identified patient may have been exposed. This suggests that the outsourcing facility must obtain information related to *all* compounded prescription preparations, *all* manufactured drug products both brand and generic, *all* dietary supplements, and *all* over-the counter medications that may have been taken by the patient as one or more or a combination thereof may be the cause of the adverse event. Essentially, the outsourcing facility would need to have full and complete access to the patient's medication records in order to comply with this requirement.

Recommendation

IACP believes that requiring information on all drug products taken by a patient that may be "suspect" is unduly burdensome to the outsourcing facility, especially given instances where a compounded preparation is distributed to a medical center where multiple treatments and therapies are provided at any given time to an individual. IACP recommends clarifying line 225 to include:

> *In all cases, including those where not all of the drug products were made by the outsourcing facility, the report would include information on all suspect drug products <u>of which the outsourcing facility is aware and has access to the necessary information for reporting.</u>*

ISSUE: Legal Access to Data

Proposed Guidance Document – Lines 251-254

As part of the adverse event report, we encourage, as appropriate, attachment of the following: (1) hospital discharge summaries, (2) autopsy reports/death certificates, (3) relevant laboratory data, and (4) other critical clinical data. In the case of a death, outsourcing facilities should also provide any available information on the event(s) that led to the death.

Comments

Since a 503B outsourcing facility may not be a health care facility (e.g., a licensed pharmacy), IACP is concerned that they may not have access or rights to these types of confidential, HIPAA protected patient health information. How does FDA interpret HIPAA and the provisions within the act which enables what is essentially equivalent to a manufacturer, distributor and/or supplier to have this information?

ISSUE: Cumbersome Reporting Process

Proposed Guidance Document – Lines 258-264

Outsourcing facilities must report adverse events using Form FDA 3500A or an alternate method in accordance with 21 CFR 310.305(d) and should submit the report to FDA as described here. FDA is currently modifying its process to specifically identify reports from outsourcing facilities and drug products compounded by outsourcing facilities. Until those actions are completed, FDA will not be able to effectively accept adverse event reports from outsourcing facilities through the electronic system, but FDA will issue additional guidance when the electronic interface is ready to accept these reports.

Comments

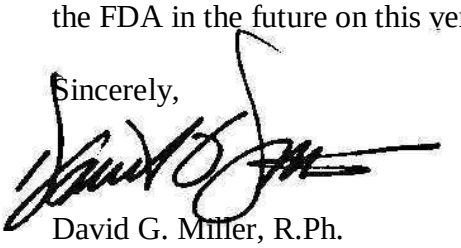
As indicated within the guidance document, FDA is not prepared or has the necessary infrastructure in place in order to receive electronic reports of adverse events despite having such a system already available for other registered entities including manufacturers. Having stated such a system is available for others, FDA is requiring physical forms and hard-copy records to be supplied by outsourcing facilities in order to comply with the 21 CFR 310.305. No timeline for the implementation of an electronic data submission is provided by the agency.

Recommendation

IACP asks that the FDA provide an implementation schedule to all currently registered outsourcing facilities outlining the anticipated date of an electronic adverse event reporting system as soon as possible.

Thank you for the opportunity to submit our comments and IACP looks forward to working with the FDA in the future on this very important issue.

Sincerely,



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