Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), student health insurance coverage is a type of individual health insurance coverage provided pursuant to a written agreement between an institution of higher education (as defined in the Higher Education Act of 1965) and a health insurance issuer, and provided to students who are enrolled in that institution and their dependents. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule provided that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS–10377 (OMB control number 0938–1157); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 52; *Total Annual Responses:* 1,176,235; *Total Annual Hours:* 52. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

Dated: December 6, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–26790 Filed 12–10–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4087]

The Food and Drug Administration's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Stakeholders, including healthcare providers (HCPs) and medical specialty groups, have expressed concerns regarding the availability of certain compounded drug products from outsourcing facilities that they would like to have on-hand as in-office supplies of non-patient-specific compounded drugs (''office stock''). The purpose of the public meeting is to provide HCPs, outsourcing facilities, entities considering becoming outsourcing facilities, and other interested parties with an opportunity to present to FDA their perspectives concerning access to office stock from outsourcing facilities in light of FDA's enforcement policies as proposed in the revised draft guidance on current good manufacturing practice (CGMP) for human drug compounding outsourcing facilities.

DATES: The public meeting will be held on May 21, 2019, from 9 a.m. to 5 p.m. Submit either electronic or written comments on this public meeting by June 21, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 21, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 21, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include Docket No. FDA–2018–N–4087 for ''FDA's Proposed Current Good Manufacturing Practice Policies for Outsourcing Facilities: Considerations Regarding Access to Office Stock.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' are publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two

copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bronwen Blass, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 301–796–5092.

SUPPLEMENTARY INFORMATION:

I. Background

A. Drug Compounding

Drug compounding is often regarded as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounded drug products serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as for a patient who has an allergy to a certain dye contained in an FDA-approved drug product and needs a medication compounded without that dye, or an elderly patient or a child who cannot swallow a pill and needs a medicine in a liquid form that is not available in an approved product. Drug products can be compounded consistent with section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) by licensed pharmacists in State-licensed pharmacies and Federal facilities, or by licensed physicians, or consistent with section 503B of the FD&C Act (21 U.S.C. 353b) by compounders known as outsourcing facilities.

Sometimes, it is necessary for HCPs in hospitals, clinics, offices, or other settings to have a certain compounded drug product on hand, so they can administer it to a patient who presents with an immediate need for the compounded drug product. Such drug products are often known as ''office stock,'' and outsourcing facilities are uniquely permitted to supply these compounded products in accordance with the law.

For example, if a patient presents at an ophthalmologist's office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the ophthalmologist may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber. In other cases, compounded drug products may need to be administered by a healthcare practitioner in his or her office because it would not be safe for the patient to take the drug home for self-administration, and it would be preferable for the physician to have the drug in his or her office to administer immediately upon diagnosis, rather than asking the physician to order the drug and have the patient return to the healthcare practitioner for administration.

Although compounded drugs can serve an important role for certain patients in cases such as these, they also can pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means they have not undergone FDA premarket review for safety, effectiveness, and quality. Because compounded drug products are subject to a lower regulatory standard than FDA-approved drug products, they present a greater risk to patients and should not be administered to patients unless their medical needs cannot be met by FDA-approved drug products.

B. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding. Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning CGMP requirements);
- section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. Among other conditions, to qualify for the exemptions under section 503A, the drug product must be compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

New section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities.* Section 503B defines *outsourcing facility,* in part, as a facility that is engaged in the compounding of sterile drugs (section 503B(d)(4)(A)(i)). An outsourcing facility may engage in nonsterile compounding provided that it also engages in the compounding of sterile drugs, and provided that it compounds all of its drugs (both sterile and nonsterile) in accordance with the conditions of section 503B.

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- Section 502(f)(1);
- section 505; and
- section 582 (21 U.S.C. 360eee–1) (concerning drug supply chain security requirements).

In contrast to compounders compounding in accordance with section 503A of the FD&C Act, outsourcing facilities may, but need not, obtain prescriptions for identified individual patients for their

compounded drug products (section 503B(d)(4)(C)). Outsourcing facilities are subject to CGMP requirements in section 501(a)(2)(B). They must also be inspected by FDA according to a risk-based schedule and are subject to specific adverse event reporting requirements and other conditions that help to mitigate the risks of the drug products they compound.

C. CGMP Requirements for Outsourcing Facilities

Elsewhere in this issue of the **Federal Register**, FDA announced the availability of a revised draft guidance for industry entitled ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' (revised draft guidance). FDA previously issued a draft guidance for industry on this subject in July 2014 (79 FR 37743). This guidance, once final, will provide for conditions under which FDA generally does not intend to take regulatory action against an outsourcing facility regarding certain CGMP requirements in 21 CFR parts 210 and 211 during the interim period before FDA issues regulations specific to outsourcing facilities. In developing policies pertaining to CGMP requirements for outsourcing facilities, FDA seeks to recognize the differences between outsourcing facilities and conventional drug manufacturers and to develop policies that reflect the specific compounding operations conducted by outsourcing facilities. The revised draft guidance proposes a risk-based approach to enforcement of CGMP requirements, tailored to the size and scope of outsourcing facilities' operations. The policies are aimed at making it more feasible for entities to register as outsourcing facilities to compound drugs for office stock in accordance with CGMP requirements, while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard drug products.

In the revised draft guidance, FDA made a number of revisions to address comments submitted on the 2014 draft. For example, the revised draft guidance differentiates between CGMP requirements applicable to sterile drug products and nonsterile drug products where appropriate. Among other changes, FDA made revisions to address comments on (1) stability testing, including the assignment of a beyond use date (BUD) as an expiration date; (2) a clear definition of ''in-use time,'' distinguishing it from ''BUD'' and ''expiration date''; (3) testing batches before release for distribution; and (4) collection and use of samples retained from distributed batches, known as reserve samples. For a more comprehensive discussion of the policies proposed in the revised draft guidance, please see the revised draft guidance (available at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*) and associated notice of availability, which FDA is publishing elsewhere in this issue of the **Federal Register**. In the docket for the revised draft guidance, FDA is seeking comment on whether the conditions outlined appropriately balance the risks and needs associated with compounded drugs produced for office stock.

II. Topics for Discussion at the Public Meeting

FDA is seeking public input regarding outsourcing facilities supplying compounded drugs for office stock in light of the CGMP policies described in the revised draft guidance, if finalized as written. FDA has developed a list of topics to facilitate a productive discussion at the public meeting. This list is not intended to be exhaustive, and FDA encourages comments on the potential implications of the policies pertaining to compliance with CGMP requirements described in the revised draft CGMP guidance, if finalized as written, for outsourcing facilities supplying drugs compounded for office stock. Policies include, but are not limited to, those related to stability studies, beyond use dating, and release testing. Issues that are of specific interest to the Agency include the following:

- Perspectives related to demand and supply of office stock, including:
  - Ways in which HCPs seek to identify outsourcing facilities that compound the drugs they want for office stock, as well as issues, if any, with this process.
  - Communications between HCPs and outsourcing facilities to address potential issues related to requested formulations, timing, and order size.
  - Coordination or consolidation of orders among providers for same or similar compounded drug products.
  - HCPs' experiences with the availability of office stock products from outsourcing facilities.
- Perspectives related to orders for drug products that an outsourcing facility has not made or does not routinely make.
  - Factors outsourcing facilities consider before deciding whether to fill an order for a requested compounded drug product that it has not previously made or does not routinely make.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities filling orders for requested products not previously or routinely made.
- Perspectives related to small volume orders of office stock products, including:
  - HCPs' experiences seeking small volume orders from outsourcing facilities.
  - Factors outsourcing facilities consider before determining whether to produce small batches of compounded drug products for office stock.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' decisions regarding filling small volume orders and/or producing small batches of compounded drug products for office stock.
  - Whether/how the revisions proposed in the revised draft guidance would affect registration of compounders engaged in smaller-scale production as outsourcing facilities.
- Perspectives related to beyond use dating for office stock products, including:
  - How long HCPs seek to keep office stock drug products before use.
  - The impact that FDA's policies proposed in the revised draft guidance would have on outsourcing facilities' production of compounded drug products for office stock with beyond use dating desired by HCPs.

FDA will post the agenda and other meeting materials at least 5 days before the meeting on the public meeting website. More information regarding the meeting, including the public meeting website address, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.*

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting must register online by May 7, 2019. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. More information regarding the meeting, including the public meeting website address and registration instructions, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.*

Registration is free and in-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each

organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8:30 a.m. We will post information at *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact *CompoundingPublicMeeting@fda.hhs.gov* no later than May 14, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. All requests to make oral presentations must be received by March 1, 2019. You will also be asked to send *CompoundingPublicMeeting@fda.hhs.gov* a brief summary your comments by March 1, 2019. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to present. For more information on oral presentation requests, visit *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.* Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin. We will do our best to accommodate all stakeholders who wish to speak; however, the duration of comments may be limited by time constraints, including time allowances for each topic. Presenters will be notified of their selection no later than May 7, 2019. If selected for presentation, any presentation materials must be emailed to the *CompoundingPublicMeeting@fda.hhs.gov* no later than May 14, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Further information regarding the webcast, including the address for the webcast, will be made available at least 2 days in advance of the meeting on the public meeting website. More information regarding the meeting, including the public meeting website address, will be posted at: *https://www.fda.gov/Drugs/NewsEvents/ucm132703.htm.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Dated: December 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–26725 Filed 12–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0779]

Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a revised draft guidance entitled ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' This revised draft guidance describes FDA's policies regarding compounders registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as outsourcing facilities and the current good manufacturing practice (CGMP) requirements in FDA regulations. Based on feedback from stakeholders and comments received on the initial draft guidance, the guidance is being revised, in part, to reflect further consideration of how CGMP requirements should be applied in light of the size and scope of an outsourcing facility's operations.

DATES: Submit either electronic or written comments on the revised draft guidance by February 11, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information under the Paperwork Reduction Act of 1995 (PRA) proposed in the revised draft guidance by February 11, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–0779 for ''Current Good Manufacturing Practice—Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information