

40 CFR Part 81

Environmental protection, Air pollution control, National parks, Wilderness areas.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 8, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AA89

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; Reopening of Comment Period

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: This document reopens the comment period for the June 17, 2015, proposed rule entitled “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation.” The comment period for the proposed rule, which ended on August 17, 2015, is reopened for 30 days.

DATES: The comment period for the proposed rule published on June 17, 2015 (80 FR 34583), is reopened and ends on May 19, 2016.

ADDRESSES: In commenting, please refer to the Regulatory Information Number (RIN) 0906-AA89, by any of the following methods. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions. The first is the preferred method.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow instructions for submitting comments. This is the preferred method for the submission of comments.

- *Email:* 340BCMPNPRM@hrsa.gov. Include 0906-AA89 in the subject line of the message.

- *Mail:* Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857.

All submitted comments will be available to the public in their entirety.

FOR FURTHER INFORMATION CONTACT: CAPT Krista Pedley, Director, OPA,

HSB, HRSA, 5600 Fishers Lane, Mail Stop 08W05A, Rockville, MD 20857, or by telephone at 301-594-4353.

SUPPLEMENTARY INFORMATION: On June 17, 2015, the Department of Health and Human Services (HHS) published a proposed rule in the **Federal Register** (80 FR 34583) entitled, “340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation” that would set forth the calculation of the ceiling price and application of civil monetary penalties for section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” In light of the comments received, HHS is reopening the comment period for 30 days for the purpose of inviting public comments on several specific areas, summarized below. Comments may be submitted on any aspect of the proposed rule, not just those areas specifically addressed below. Commenters do not need to resubmit comments previously submitted, as all previous comments are currently under review and will be considered prior to the finalization of the proposed rule.

Ceiling Price for a Covered Outpatient Drug Exception

In the June 17, 2015, notice of proposed rulemaking (80 FR 34583), HHS proposed that when the calculation of the 340B ceiling price resulted in an amount less than \$0.01, the ceiling price would be \$0.01 per unit of measure (hereinafter, penny pricing). In the notice of proposed rulemaking (NPRM), we recognized that it was not reasonable for a manufacturer to set the ceiling price at \$0.00 per unit of measure. HHS received a number of comments supporting and opposing the penny pricing proposal.

Commenters suggested a number of alternatives to penny pricing, including: The federal ceiling price, the most recent positive ceiling price from previous quarters, and nominal sales price. Some commenters stated that the federal ceiling price, which is the basis for prices paid by certain federal government programs, would be a viable alternative. Other commenters suggested that charging a ceiling price from previous quarters in which the ceiling price was greater than \$0.00 would be reasonable. Finally, several commenters suggested that nominal pricing, which is a term used in the Medicaid Drug Rebate Program, would be more appropriate. Other commenters suggested that manufacturers should be able to utilize any other reasonable alternative.

Given these comments, HHS is considering whether any of these alternatives or other alternatives not raised by the commenters, alone or in combination, would be more appropriate than the penny pricing proposal and whether to revise the proposed regulatory text in 42 CFR 10.10(b). As the NPRM did not indicate that alternatives to the penny pricing proposal would be considered, and given the number of comments on this issue, HHS is reopening the comment period specifically to invite comments on whether we should adopt an alternative policy to penny pricing. By reopening the comment period as to this specific issue, all parties will have an opportunity to express their views on penny pricing and other alternatives prior to finalization of the proposed rule.

New Drug Price Estimation

In the NPRM, HHS proposed that manufacturers estimate the ceiling price for a new covered outpatient drug as of the date the drug is first available for sale, and provide HRSA an estimated ceiling price for each of the first three quarters the drug is available for sale. HHS also proposed that, beginning with the fourth quarter the drug is available for sale, the manufacturer must calculate the ceiling price as described in proposed 42 CFR 10.10(a). Under the proposed rule, the actual ceiling price for the first three quarters must also be calculated and manufacturers would be required to provide a refund or credit to any covered entity which purchased the covered outpatient drug at a price greater than the calculated ceiling price. HHS proposed that any refunds or credits owed to a covered entity must be provided by the end of the fourth quarter. HHS received numerous comments supporting and opposing the various components of its proposal on new drug price estimation.

Several commenters supported a specific methodology for calculating new drug prices, which included setting the price of the new covered outpatient drug as wholesale acquisition cost (WAC) minus the applicable rebate percentage (*i.e.*, 23.1 percent for most single-source and innovator drugs, 17.1 percent for clotting factors and drugs approved exclusively for pediatric indications, and 13 percent for generics and OTCs). Commenters argued that this price would eliminate the need to estimate the price for the first three quarters and would result in a reasonable ceiling price. We are seeking comment on this specific methodology for the estimation of a new covered outpatient drug pricing and at which

quarter a manufacturer should refund or credit a covered entity if there is an overcharge.

Definition of “Knowing and Intentional”

Under section 340B(d)(1)(B)(vi) of the Public Health Service Act, the Secretary is charged with issuing civil monetary penalties for manufacturers who have “knowingly and intentionally” charged a covered entity a price that exceeds the 340B ceiling price. Although the knowing and intentional standard was included in the NPRM issued on June 17, 2015, “knowing and intentional” was not specifically defined. HHS received a number of comments urging HHS to further define these terms. Through this reopening of the NPRM comment period, we are seeking comment on the definition of the knowing and intentional standard for purposes of this civil monetary penalty authority. We believe that, by reopening the comment period as to this issue, all parties will have an opportunity to express their views on this definitional standard prior to finalization of the rule.

HHS is considering whether “knowing and intentional” should be further defined. If the terms are defined, possible definitions could be: (1) Actual knowledge by the manufacturer, its employees, or its agents of the instance of overcharge; (2) willful or purposeful acts by, or on behalf of, the manufacturer that lead to the instance of overcharge; (3) acting consciously and with awareness of the acts leading to the instance of overcharge; and/or (4) acting with a conscious desire or purpose to cause an overcharge or acting in a way practically certain to result in an overcharge. Manufacturers do not need to intend specifically to violate the 340B statute; but rather to have knowingly and intentionally overcharged the 340B covered entity.

HHS understands that this is difficult to demonstrate. As such, HHS is soliciting input on circumstances in which the requisite intent should and should not be inferred. In particular, HHS would like to solicit comment on the concept that manufacturers would not be considered to have the requisite intent in the following circumstances:

- The manufacturer made an inadvertent, unintentional, or unrecognized error in calculating the ceiling price;
- A manufacturer acted on a reasonable interpretation of agency guidance; or
- When a manufacturer has established alternative allocation procedures where there is an inadequate supply of product to meet market

demand, as long as covered entities are able to purchase on the same terms as all other similarly-situated providers.

HHS welcomes comments regarding other situations where the requisite intent may or may not be demonstrated.

Because of the scope of the proposed rule, and since we have specifically requested the public’s comments on various aspects of the rule, we believe that it is important to allow ample time for the public to consider these approaches to these specific policies in the proposed rule. Therefore, we have decided to reopen the comment period for an additional 30 days. HHS believes that a 30-day period is sufficient and balances the interests of encouraging public participation in the rulemaking process with the desire to not unnecessarily delay key decisions about rulemaking. This document announces the reopening of the comment period to end May 19, 2016.

Dated: April 6, 2016.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: April 12, 2016.

Sylvia M. Burwell,

Secretary.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2012–0097; 4500030114]

RIN 1018–AZ74

Endangered and Threatened Wildlife and Plants; Proposed Rule To Amend the Listing of the Southern Selkirk Mountains Population of Woodland Caribou

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the public comment period on our May 8, 2014, proposed rule to amend the listing of the southern Selkirk Mountains population of woodland caribou (*Rangifer tarandus caribou*) by defining the Southern Mountain Caribou distinct population segment (DPS) and listing it as threatened. In the May 8, 2014, proposed rule, we also proposed to

reaffirm our November 28, 2012, final designation of critical habitat for the southern Selkirk Mountains population of woodland caribou as critical habitat for the proposed Southern Mountain Caribou DPS. On March 23, 2015, the U.S. District Court of Idaho remanded our November 28, 2012, final critical habitat rule to the Service to correct a procedural error by providing another opportunity for public comment. This reopening of the comment period will provide all interested parties with the opportunity to provide comment on our November 28, 2012, final critical habitat designation, in light of the court’s ruling.

DATES: The comment period for the proposed rule published in the **Federal Register** on May 8, 2014 (79 FR 26504), is reopened. We will consider comments received or postmarked on or before May 19, 2016. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. Any comments that we receive after the closing date may not be considered in the final decision on this action.

ADDRESSES:

Document availability: You may obtain information and documents associated with the opening of this comment period, a copy of the November 28, 2012, final critical habitat designation (77 FR 71042), as well as information relating to the proposed reaffirmation of critical habitat in the proposed amended listing rule (79 FR 26504, May 8, 2014) and any comments received on that rule at <http://www.regulations.gov> under Docket No. FWS–R1–ES–2012–0097, or by contacting the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). Information we relied upon for making our November 28, 2012, final critical habitat designation (77 FR 71042) can be found at <http://www.regulations.gov> under Docket No. FWS–R1–ES–2011–0096 and Docket No. FWS–R1–ES–2012–0097, or by contacting the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Comment submission: You may submit written information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: <http://www.regulations.gov>. In the Search box, enter FWS–R1–ES–2012–0097, which is the docket number for this rulemaking. Then, click the Search button. In the Search panel on the left side of the