

Chart”). The Rule was promulgated to maximize use of the route, as published per the Chart, to secure and improve upon decreased levels of noise that had been voluntarily achieved.¹ Under the Rule, pilots are permitted to deviate from the route and altitude requirements when necessary for safety, weather conditions, or transitioning to or from a destination or point of landing.

The Rule originally had a two-year duration and was set to terminate on August 6, 2014. The FAA limited the duration of the Rule because, at the time of promulgation, the FAA did not have data on the current rate of compliance with the voluntary route nor the circumstances surrounding an operator’s decision not to use the route. The FAA concluded there would be no reason to retain the Rule if the FAA determined helicopter noise along the North Shore of Long Island did not improve. Accordingly, the Agency decided that the Rule would expire in two years, if it was determined there is no meaningful improvement in the effects of helicopter noise on quality of life or that the Rule was otherwise unjustified. Specifically, the FAA stated that should there be such an improvement, the FAA may, after appropriate notice and opportunity for comment, decide to make the Rule permanent. Likewise, should the FAA determine that reasonable modification could be made to the route to better address noise concerns (and any other relevant concerns), the FAA may choose to modify the Rule after notice and comment.

On June 23, 2014, the FAA issued a two-year extension of the Rule’s termination date (79 FR 35488), and on July 25, 2016 the FAA issued a four-year extension of the Rule’s termination date (81 FR 48323). The Rule is scheduled to expire on August 6, 2020.

As explained in the Rule, helicopters are generally limited in the distance they can prudently operate from shore without being equipped for overwater operations because they are not able to glide for any significant distance in the event of a total loss of power.

At the time of the original rulemaking, the FAA estimated that two-thirds of commercial helicopters operating along the north shore were equipped with multiple engines. This equipment allowed for a route to be established a little farther off shore than what would be prudent in an area where single-engine

helicopters are predominantly operated; however, there are still significant safety implications with pushing all helicopter traffic farther over the water. Allowing helicopters to operate within sight of the coastline provides pilots with multiple visual waypoints by which to safely navigate along the north shore. The route was designed to avoid the potential safety implications associated with helicopters flying in VFR conditions off the coastline and the interaction with other traffic at or above the route’s specified altitude.

The FAA is inviting comments that may assist the agency in assessing and understanding the impacts of the Rule and any potential implications of modifying the Rule. In particular, we invite responses to the following questions:

1. Did implementation of the Rule result in more or less helicopter noise in your community compared to levels you experienced prior to implementation of the Rule?
2. How and when do helicopter operators deviate from the Rule?
3. Are there alternative or supplemental routes that you believe will reduce the noise impacts without jeopardizing the safe operation of aircraft?
4. Should the Rule be extended, modified, or allowed to expire in 2020?

Issued under authority provided by Public Law 115–254, 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on October 29, 2018.

Daniel K. Elwell,

Acting Administrator.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

RIN 2120–AK39

Notification of Public Meetings on Requirement for Helicopters To Use the New York North Shore Helicopter Route

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notification of public meetings.

SUMMARY: The FAA announces three public meetings to solicit feedback concerning the New York North Shore Helicopter Rule (“the Rule”). These meetings are being held pursuant to Section 182 of the FAA Reauthorization Act of 2018. The Rule requires civil helicopter pilots operating under Visual

Flight Rules (VFR), whose route of flight takes them over the north shore of Long Island between the Visual Point Lloyd Harbor (VPLYD) waypoint and Orient Point (VPOLT), to use the North Shore Helicopter Route.

DATES: The public meetings will be held on November 13, November 14, and November 15, 2018.

ADDRESSES: The public meetings will be held at the following sites:

November 13, 2018, 7–9 p.m.—Cradle of Aviation Museum, Charles Lindbergh Blvd., Garden City, NY 11530.

November 14, 2018, 7–9 p.m.—Riverhead Middle School, 600 Harrison Avenue, Riverhead, NY 11901.

November 15, 2018, 7–9 p.m.—Vaughn College, 8601 23rd Ave, Flushing, NY 11369.

FOR FURTHER INFORMATION CONTACT:

Christopher Bailey, Office of Rulemaking, Federal Aviation Administration; telephone (202) 267–4158; email *Christopher.bailey@faa.gov*.

SUPPLEMENTARY INFORMATION:

Purpose of the Public Meetings

The purpose of the public meetings is for the FAA to obtain feedback relevant to the Rule at subpart H of part 93, which requires civil helicopter pilots operating under VFR, whose route of flight takes them over the north shore of Long Island between the VPLYD waypoint and VPOLT, to use the North Shore Helicopter Route. The FAA will consider comments made at the public meetings in its review of the Rule.

Public Participation and Meeting Procedures

The meetings will use a workshop format. FAA will have several stations covering a number of relevant aspects of the Rule. Each station will be staffed by a representative of the FAA who is able to answer questions regarding that subject. There will also be a station where the public can submit a written statement or have their oral comment transcribed. No formal presentations will be made.

Section 182 of the FAA Reauthorization Act of 2018 also calls for a written comment period on the North Shore Helicopter Rule. See the document published elsewhere in this issue of the **Federal Register**, titled Request for Comments on Requirement for Helicopters to Use the New York North Shore Helicopter Route, under docket number FAA–2018–0954, for information regarding submitting written comments on the Rule to the **Federal Register**.

Sign and oral interpretation can be made available at the meeting, as well

¹ The rule is based on a voluntary VFR route that was developed by the FAA working with the Eastern Region Helicopter Council. The voluntary route originally was added to the Chart on May 8, 2008.

as an assistive listening device, if requested 10 calendar days before the meeting. The meetings will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

Issued in Washington, DC, on October 30, 2018.

Brandon Roberts,

Deputy Executive Director, Office of Rulemaking.

[FR Doc. 2018-24129 Filed 11-1-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906-AB19

340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking; effective date change.

SUMMARY: The Health Resources and Services Administration (HRSA) administers section 340B of the Public Health Service Act (PHSA), which is referred to as the “340B Drug Pricing Program” or the “340B Program.” HRSA published a final rule on January 5, 2017, that set forth the calculation of the 340B ceiling price and application of civil monetary penalties.

On June 5, 2018, HRSA published a final rule that delayed the effective date of the 340B ceiling price and civil monetary rule until July 1, 2019, to allow a more deliberate process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for additional rulemaking. After further consideration of the issue, the Department of Health and Human Services (HHS or Department) proposes to cease any further delay of the rule and change the effective date from July 1, 2019, to January 1, 2019.

DATES: Submit comments on or before November 23, 2018

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906-AB19, 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-AB19 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. Please do not submit commercial confidential information or personal identifying information that you do not want in the public domain.

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:

I. Background

HHS published a notice of proposed rulemaking (NPRM) in June 2015 to implement civil monetary penalties (CMPs) for manufacturers who knowingly and intentionally charge a covered entity more than the ceiling price for a covered outpatient drug; to provide clarity regarding the requirement that manufacturers calculate the 340B ceiling price on a quarterly basis and how the ceiling price is to be calculated; and to establish the requirement that a manufacturer charge a \$.01 (penny pricing policy) for drugs when the ceiling price calculation equals zero (80 FR 34583, (June 17, 2015)). The public comment period closed on August 17, 2015, and HRSA received 35 comments. After review of the initial comments, HHS reopened the comment period (81 FR 22960, (April 19, 2016)) to invite additional comments on the following areas of the NPRM: 340B ceiling price calculations that result in a ceiling price that equals zero (penny pricing); the methodology that manufacturers use when estimating the ceiling price for a new covered outpatient drug; and the definition of the “knowing and intentional” standard to be applied when assessing a CMP for manufacturers that overcharge a covered entity. The comment period closed May 19, 2016, and HHS received 72 comments.

On January 5, 2017, HHS published a final rule in the **Federal Register** (82 FR 1210, (January 5, 2017)). Comments from both the NPRM and the reopening notice were considered in the development of the final rule. The provisions of that rule were to be effective March 6, 2017; however,

through a series of rules, HHS delayed the effective date of the January 5, 2017 final rule until July 1, 2019 (83 FR 25943, June 5, 2018).

II. Proposal To Change the Effective Date of the Final Rule From July 1, 2019, to January 1, 2019

HHS proposes to cease any further delay of the January 5, 2017 final rule and to change the effective date from July 1, 2019, to January 1, 2019. As the effective date will be the first day of the quarter, the implementation date and the effective date will be the same. In its most recent rulemaking delaying the effective date of the January 5, 2017 final rule, HHS stated that it “is developing new comprehensive policies to address the rising costs of prescription drugs. These policies will address drug pricing in government programs, such as Medicare Parts B & D, Medicaid, and the 340B Program. Due to the development of these comprehensive policies, we are delaying the effective date for the January 5, 2017, final rule to July 1, 2019.” (83 FR 25944)

The Department has determined that the finalization of the 340B ceiling price and civil monetary penalty rule will not interfere with the Department’s development of these comprehensive policies. Accordingly, the Department no longer believes a delay in the effective date is necessary and is proposing to change the effective date of the rule from July 1, 2019, to January 1, 2019.

The provisions included in the January 5, 2017 final rule were subject to extensive public comment, and have been delayed several times. As such, HHS believes that it has considered the full range of comments on the substantive issues in the January 5, 2017 final rule.

HHS believes that finalization of this proposed change to the effective date of the January 5, 2017 final rule would satisfy its obligation to implement the statutory provisions enacted by Congress in 2010 to create civil monetary penalties.

HHS seeks public comments specifically regarding the impact of ceasing any further delay of the January 5, 2017 final rule, including any potential disruptions to implementation, and changing the effective date from July 1, 2019, to January 1, 2019.

HHS encourages all stakeholders to provide comment on this proposed rule. A comment period of 21 days is sufficient to provide affected parties the opportunity to provide their views as this rule is uncomplicated and simply