(ii) Usability testing and a labeling comprehension study must demonstrate that the clinician can correctly select and use the device, as identified in the labeling, based on reading the directions for use.

(iii) The elements of the device that may contact the patient must be demonstrated to be biocompatible.

(iv) Performance data must demonstrate the sterility of the device.

(v) Validation of cleaning and sterilization instructions must demonstrate that any reusable device components can be safely and effectively reprocessed per the recommended cleaning and sterilization protocol in the labeling.

(vi) Performance data must support the shelf life of the device by demonstrating continued device functionality, sterility, and package integrity over the identified shelf life.

(vii) Labeling of the device must include the following:

(A) Unless data demonstrates the safety of doing so, contraindications must be identified regarding use of the device on tissues for which the risk of stapling outweighs any reasonably foreseeable benefit due to known complications, including the stapling of necrotic or ischemic tissues and tissues outside of the labeled limits of tissue thickness.

(B) Unless available information demonstrates that the specific warnings do not apply, the labeling must provide appropriate warnings regarding how to avoid known hazards associated with device use including:

(*i*) Avoidance of obstructions to the creation of the staple line and the unintended stapling of other anatomic structures;

(*ii*) Avoidance of clamping and unclamping of delicate tissue structures to prevent tissue damage;

(*iii*) Avoidance of use of the stapler on large blood vessels, such as the aorta;

(*iv*) Establishing and maintaining proximal control of blood vessels prior to stapling;

(*v*) Appropriate measures to take if a stapler malfunction occurs while applying staples across a blood vessel, such as clamping or ligating the vessel before releasing the stapler, while the stapler is still closed on the tissue; and

(*vi*) Ensuring stapler compatibility with staples.

(C) Specific user instructions for proper device use including measures associated with the prevention of device malfunction, evaluation of the appropriateness of the target tissue for stapling, and evaluation of the resultant staple line.

(D) List of staples with which the stapler has been demonstrated to be compatible.

(E) Identification of key performance parameters and technical characteristics of the stapler and the compatible staples needed for safe use of the device.

(F) Information regarding tissues on which the stapler is intended to be used.

(G) Identification of safety mechanisms of the stapler.

(H) Validated methods and instructions for reprocessing of any reusable device components.

(I) An expiration date/shelf life.

(viii) Package labels must include critical information and technical characteristics necessary for proper device selection.

■ 3. In § 878.4800, revise paragraph (a) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

(a) *Identification.* A manual surgical instrument for general use is a nonpowered, hand-held, or hand-manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. The device includes the applicator, clip applier, biopsy brush, manual dermabrasion brush, scrub brush, cannula, ligature carrier, chisel, clamp, contractor, curette, cutter, dissector, elevator, skin graft expander, file, forceps, gouge, instrument guide, needle guide, hammer, hemostat, amputation hook, ligature passing and knot-tying instrument, knife, blood lancet, mallet, disposable or reusable aspiration and injection needle, disposable or reusable suturing needle, osteotome, pliers, rasp, retainer, retractor, saw, scalpel blade, scalpel handle, one-piece scalpel, snare, spatula, disposable or reusable stripper, stylet, suturing apparatus for the stomach and intestine, measuring tape, and calipers. A surgical instrument that has specialized uses in a specific medical specialty is classified in separate regulations in parts 868 through 892 of this chapter.

* * * * *

Dated: April 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08260 Filed 4–23–19; 8:45 am]

BILLING CODE 4164–01–P

POSTAL SERVICE

39 CFR Part 551

Definition of Private Carrier for Premium PO Box Delivery

AGENCY: Postal Service™.

ACTION: Advanced Notice of Proposed Rulemaking.

SUMMARY: The Postal Service seeks customer and other stakeholder feedback to define the phrase ''packages from private carriers,'' as used in connection with PO Box Street Addressing. The Postal Service is contemplating an amendment to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) to clarify the Street Addressing Additional Service available at many Premium Post Office Box Service locations.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Mail or deliver written comments to the Manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. Email comments and questions to *ProductClassification@usps.gov* using the subject line ''Street Addressing at Premium PO Box Service Locations.'' Faxed comments will not be accepted.

FOR FURTHER INFORMATION CONTACT: Derek F. Hatten, Sr. Retail Services Specialist, Retail Partners and Services, 202–268–6919, *derek.f.hatten@usps.gov.*

SUPPLEMENTARY INFORMATION: On June 17, 2010, the Postal Regulatory Commission (PRC) approved the initial request of the Postal Service to transfer some Post Office Box (PO Box™) Service locations from the market dominant list to the competitive product list (see Order No. 473, Order Approving Request to Transfer Selected Post Office Box Service Locations to the Competitive Product List, PRC Docket No. MC2010–20). Additional locations were transferred following PRC approval in subsequent Order No. 780, Order Approving Request to Transfer Additional Post Office Box Service Locations to the Competitive Product List, PRC Docket No. MC2011–25 (Jul. 29, 2011). At these locations, the Postal Service now provides some of the same services offered by its competitors. These ''Additional Services,'' which are available at Premium PO Box service locations (formerly referred to as ''Move To Competitive'' locations) for no additional fee above the PO Box fees, include a service called ''Street Addressing.''

On February 14, 2013, language was added to the Mail Classification Schedule (MCS) describing the Street Addressing feature, including the option of receiving ''packages from private carriers'' (see Order No. 1657, Order on Elective Filing Regarding Post Office Box Service Enhancements, PRC Docket

No. MC2012–26; MCS § 2640.1.g). In related proceedings, the Postal Service explained that the delivery of private carrier packages would provide a service frequently requested by its customers, addressing a concern posed by the fact that some eCommerce merchants will not ship to a PO Box address (See *id.* at 6). A description of the Street Addressing feature was subsequently added to DMM 508.4.5.4.a, which states that customers who choose to use the street addressing designation also have the option of receiving packages from private carriers at the customer's Post Office Box address, if the packages conform to the maximum standards of 70 pounds in weight and 130 inches in combined length and girth. The street addressing feature may be used when the merchant or retailer does not accept the PO Box address format as a deliverable address.

When the Postal Service first introduced PO Box Street Addressing, there were very few private carriers or delivery competitors who would deliver packages to a PO Box customer. This made it simple for Premium PO Box Post Offices to accept and deliver packages that bore the street address equivalent of the PO Box address. They could easily recognize a private carrier, and accept and deliver the PO Box customer's packages with little concern as to whether the carrier was legitimate or the customer actually had requested that the package be delivered to the PO Box. However, as the shipping and delivery industry has evolved, so has the competition for last mile delivery.

Since the introduction of PO Box Street Addressing, a number of pilot efforts have aimed to reduce the delivery time of packages to the customer. These efforts include, but are not limited to, employees delivering packages using their personally owned vehicles, online retailers creating their own delivery operations, and retailers using crowdsourcing or taxi services to deliver packages. Where once the term ''private carriers'' would be commonly understood to include traditional shipping providers such as UPS and FedEx, now there are many more delivery options, including ''regional'' delivery companies such as LaserShip and localized or crowdsourced delivery startups such as PostMates and Deliv. Not all employees or persons who might deliver a package to a PO Box wear uniforms or are readily identified as being associated with a legitimate ''private carrier.'' Nor do all items submitted for delivery meet the traditional definition of a ''package'' according to Postal Service mailability standards. As one example, some Post Offices have been asked to accept open, tote-style shopping bags containing merchandise, in lieu of a sealed box or envelope. Others have been presented with packages labeled only with the customer's name but without the street address, and delivered by employees or contractors of a merchant with no clear indication of where the package originated.

As a practical matter, the advances in last mile delivery have created confusion as to who may deliver packages to a Premium PO Box customer when the customer uses the street address equivalent of their PO Box address to order merchandise. Therefore, the Postal Service seeks input on how the term ''private carriers,'' as used in DMM 508.4.5.4.a, should be defined, and how best to clarify that only properly sealed items mailed as a ''package'' may be delivered. These clarifications are necessary to ensure that Postal Service employees follow proper procedures, which helps prevent fraud and ensures the safety and security of customers and Postal Service personnel.

We will publish an appropriate amendment to 39 CFR part 551 if the Postal Service adopts any changes to the definition of ''packages from private carriers,'' as used in connection with Street Addressing, in DMM 508.4.5.4.a.

Ruth B. Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2019–08222 Filed 4–23–19; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2019–0036; FRL–9992–64–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Infrastructure Requirements for the 2015 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submittal from the State of Maryland for the 2015 ozone national ambient air quality standard (NAAQS or standard). Whenever EPA promulgates a new or revised NAAQS, states are required to make a SIP submission showing how the existing approved SIP has all the provisions necessary to meet the requirements of the new or revised NAAQS, or to add any needed provisions necessary to meet the revised NAAQS. The SIP revision is required to address basic program elements, including, but not limited to, regulatory structure, monitoring, modeling, legal authority, and adequate resources necessary to assure attainment and maintenance of the standards. These elements are referred to as infrastructure requirements. Maryland has made a submittal addressing the infrastructure requirements for the 2015 ozone NAAQS. EPA is proposing to approve Maryland's SIP revision addressing the infrastructure requirements for the 2015 ozone NAAQS in accordance with the requirements of section 110(a) of the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 24, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2019–0036 at *http://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, Planning and Implementation Branch (3AD30), Air and Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5787. Ms. Schmitt can also be reached via