DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, 419, 424, 485, 488, 489

Office of the Secretary

45 CFR Part 180

[CMS–1786–P]

RIN 0938–AV09

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year 2024 based on our continuing experience with these systems. In this proposed rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. This proposed rule also would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. This proposed rule would also establish payment for certain intensive outpatient services under Medicare, beginning January 1, 2024. In addition, this proposed rule would update and refine requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency. We also propose to codify provisions of the Consolidated Appropriations Act, 2023, in Community Mental Health Centers Conditions of Participation (CoPs). We propose to revise the personnel qualifications of Mental Health Counselors and add personnel qualifications for Marriage and Family Therapists in the CMHC CoPs. We also seek comment on separate payment under the Inpatient Prospective Payment System (IPPS) for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. Finally, we propose to address any future revisions to the IPPS Medicare Code Editor (MCE), including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. Additionally, we propose a technical correction to the Rural Emergency Hospital Conditions of Participation.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 11, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1786–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–P, P.O. Box 8010, Baltimore, MD 21244–1810.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Elise Barringer, *Elise.Barringer@cms.hhs.gov* or 410–786–9222.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *marsha.hertzberg@cms.hhs.gov*.

Biosimilars Packaging Exception, contact Gil Ngan via email at *gil.ngan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov*.

Community Mental Health Centers (CMHC) Conditions of Participation, contact Mary Rossi-Coajou via email at *Mary.RossiCoajou@cms.hhs.gov* or Cara Meyer via email at *Cara.Meyer@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

COVID–19 Final Rules, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email *Kimberly.Go@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Hospital Price Transparency (HPT), contact Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Inpatient Prospective Payment System (IPPS) Medicare Code Editor, contact Mady Hue via email at *Marilu.Hue@cms.hhs.gov*.

Mental Health Services Furnished Remotely by Hospital Staff to

that CERAMENT® G meets the third cost significance requirement.

We are inviting public comment on whether the CERAMENT® G meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScopeTM 5 Broncho HD

Ambu Inc. submitted an application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD for CY 2024. Per the applicant, the Ambu® aScope™ 5 Broncho HD is one component of the Ambu® aScope™ 5 Broncho HD System which consists of: (1) the Ambu® aScope™ 5 Broncho HD (5.0/2.2 or 5.6/2.8), a sterile, single-use, disposable flexible/rigid bronchoscope; and (2) Ambu® aBox™ 2, a compatible, reusable display unit. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD component.

Per the applicant, the Ambu® aScope™ 5 Broncho HD, consists of: (1) a handle, to hold the scope (designed for left and right hand); (2) a control lever, to move the distal tip up or down in a single plane; (3) a working channel and working channel port, for instillation of fluids and insertion of endotherapy instruments; (4) a biopsy valve, to be attached to the working channel port, for insertion of endotherapy instruments or attachment of a syringe; (5) a suction connector, for connection of suction tubing; (6) a suction button, to activate suction when pressed; (7) endoscope buttons 1 and 2 (depending on settings in display unit the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, initiate advanced red contrast (ARC), and zoom); (8) a rotation control ring, for rotation of the insertion cord during procedure; (9) a tube connection, for fixation of tubes with standard connector during procedure; (10) an insertion cord and insertion portion, flexible airway insertion cord; (11) bending section, maneuverable part; (12) distal tip, which contains the camera, light source (two light-emitting diodes (LEDs)), and the working channel exit; (13) display unit connector, to connect to the port on the Ambu® aBox™ 2 display unit; (14) a cable, to transmit the image signal to the Ambu® aBox™ 2 display unit; (15) a protective handle cover, to protect the control lever during transport and storage; (16) a protective pipe, to protect the insertion cord during transport and storage; and (17) an introducer, to facilitate introduction of luer lock syringes.

The applicant stated that the Ambu® aScope™ 5 Broncho HD is an imaging/illumination bronchoscope device that uses an integrated camera module and built-in dual LED illumination to provide access to, and imaging of, the lungs for diagnostic and therapeutic purposes for pulmonology patients. The device is intended for endoscopy and endoscopic surgery within the lungs, also known as bronchoscopy. According to the applicant, the Ambu® aScope™ 5 Broncho HD was designed to perform a wide array of diagnostic and interventional pulmonology procedures. The applicant noted that the Ambu® aScope™ 5 Broncho HD is a single-use bronchoscope designed to be used with the Ambu® aBox™ 2 display unit, endotherapy instruments, and other ancillary equipment for bronchoscopic procedures and examination within the airways and the tracheobronchial tree. It is intended to provide visualization via the compatible display unit, the Ambu® aBox™ 2, and to allow passage of endotherapy instruments via its working channel.

Per the applicant, the Ambu® aScope™ 5 Broncho HD bronchoscope is inserted into the patient airway through either the mouth, nose, or via a tracheostomy, if present. The applicant explained that when the Ambu® aScope™ 5 Broncho HD bronchoscope has reached the correct position, endotherapy instruments can be inserted into the working channel system of the bronchoscope. Per the applicant, an introducer supplied with the bronchoscope can be attached to the working channel port via a luer lock adaptor, while the bronchoscope is in use. The applicant noted that the suction system may be used to remove blood, saliva, and mucus from the airway. The applicant indicated that a bronchoscope operator monitors the field of view via the integrated camera of the Ambu® aScope™ 5 Broncho HD bronchoscope and the procedure is finished when the device is pulled out completely.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 25, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ 5 Broncho HD as a device to be used for endoscopic procedures and examination within the airways and tracheobronchial tree. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Ambu® aScope™ 5 Broncho HD is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted as required by § 418.66(b)(3).

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether the Ambu® aScope™ 5 Broncho HD is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the Ambu® aScope™ 5 Broncho HD is a supply or material furnished incident to a service.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described the Ambu® aScope™ 5 Broncho HD as a single-use, disposable, digital flexible/rigid bronchoscope that is used in pulmonary procedures (bronchoscopy) to diagnose and treat conditions of the lungs, including tumors or bronchial cancer, airway blockage (obstruction), narrowed areas in airways (strictures), inflammation, and infections such as tuberculosis (TB), pneumonia, fungal or parasitic lung infections, interstitial pulmonary disease, causes of persistent cough, causes of coughing up blood, spots seen on chest X-rays, and vocal cord paralysis. The applicant claimed that the Ambu® aScope™ 5 Broncho HD is different from other endoscopes because it is a single-use endoscope indicated

for use in the respiratory system, the device records snapshots or video of images, and the device is temporarily inserted into the patient airway to diagnose and treat lung problems. According to the applicant, there are two possible existing pass-through device categories, represented by the following codes: C1748 (Endoscope, single-use (*i.e.,* disposable), upper gastrointestinal tract (GI), imaging/illumination device (insertable)); and C1747 (Endoscope, single-use (*i.e.,* disposable), urinary tract, imaging/illumination device (insertable)). The applicant noted that while these two codes are for single-use endoscopic devices, they are only appropriate for GI and urinary tract imaging, respectively. Therefore, the applicant asserted that these two codes would not apply to a single-use, disposable, bronchoscopy for use in pulmonary procedures. We note that while C1748 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies by: (1) elimination of complex cleaning/reprocessing procedures, (2) reduction of microbial transmission and infection since it is single-use, (3) elimination of the need for continuous training of reprocessing staff, (4) minimization of the risk of patient cross-contamination, (5) assurance that a sterilized scope will be used each time, and (6) assurance that there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates complex cleaning/reprocessing procedures because it is a single-use device, the applicant referenced an FDA Reprocessing Final Guidance document [16] issued March 17, 2015. This FDA document provides guidance to medical device manufacturers on the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The guidance document is limited to reusable medical devices and single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use. In this guidance document, FDA identifies a subset of reusable medical devices (including bronchoscopes and accessories) that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed and indicates design features which may pose a challenge to adequate reprocessing for arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories. However, the FDA guidance does not mention sterile, single-use medical devices in this document.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD reduces microbial transmission and infection because it is single-use, the applicant referenced an FDA safety notice [17] issued on September 17, 2015 (2015 FDA safety notice). The FDA notice discussed the findings of an investigation into infections associated with reprocessed reusable medical devices, including an analysis of Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care facilities. The notice provided that between January 2010 and June 2015, FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. However, FDA noted that, when compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. In 2014, FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation of this issue. FDA indicated that a small number of the reported infections were from persistent device contamination despite following the manufacturer's reprocessing instructions, however, most of the infections were the result of the failure to meticulously follow manufacturer instructions for reprocessing, or continued use of devices despite integrity, maintenance, and mechanical issues. FDA provides additional recommendations for health care facilities and staff that reprocess flexible bronchoscopes and patients considering bronchoscopy procedures, but does not reference single-use bronchoscopes in the notice.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates the need for continuous training of reprocessing staff, the applicant referenced a study by Châteauvieux et al.,[18] which assessed the organizational and economic impacts of the introduction of a single-use flexible bronchoscope (FB) (Ambu® aScope™, versions 2 and 3) in comparison with a reusable FB (Pentax®) at the hospital level. The study took place between May 2016 and October 2016 in the Georges Pompidou European Hospital, an 800-bed university hospital in France. Châteauvieux et al. noted that the introduction of single-use FBs led to a more simplified process, less stress for medical and paramedical staff in emergency situations, teaching benefits, and easier management of transport, in comparison with reusable FBs. However, the authors recommended limiting the use of single-use FBs to specific situations, and to prioritize the use of reusable devices for most of the bronchoscopies for cost savings.

The applicant referred to a meta study by Barron and Kennedy[19] to support its

[16] FDA Guidance March 17 2015 ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff'' *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf.*

[17] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[18] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[19] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy,*

claim that the use of Ambu® aScope™ 5 Broncho HD minimizes the risk of patient cross-contamination, ensuring that health care providers have taken optimal steps to safeguard their patients. Barron and Kennedy summarized the major advantages of single-use FBs over the standard reusable FBs in clinical scenarios. The authors noted that single-use FBs offer a safer alternative to standard reusable FBs in specific scenarios where reduced risk of cross infection was critical in the immunocompromised patient and in rare cases of prior contamination due to transmissible spongiform encephalopathies.

The applicant referred to a self-sponsored study [20] by Ofstead et al.[21] in 2019, in support of its claim that the use of the Ambu® aScope™ 5 Broncho HD ensures a sterilized scope is available for each procedure while reusable endoscopes may not be sterile even if manufacturers' cleaning protocols are followed. The study first referenced Ofstead et al.'s 2017 [22] evaluation of the effectiveness of bronchoscope processing in three large hospitals where every bronchoscope had visible defects, protein was detected on 100 percent of high-level disinfected bronchoscopes, and bacteria or mold were found on 58 percent of the patient-ready bronchoscopes. Then, in 2019, Ofstead et al. conducted the study to determine the time and cost of acquiring, maintaining, and reprocessing bronchoscopes in four hospitals (two in the Midwest and two in the West Coast). Three hospitals had obtained single-use Ambu® bronchoscopes (2018, version unspecified) for procedures done in certain departments, after hours, or in emergency situations. Per Ofstead et al. (2019), the cost for procedures with reusable bronchoscopes ($281 to $803) were comparable or higher than the cost of single-use bronchoscopes ($220 to $315), due to acquisition and maintenance of large inventories of bronchoscopes to ensure real-time availability for various hospital departments. Ofstead et al. (2019) suggested the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities. Ofstead et al. (2019) summarized the steps that can be taken to reduce risks related to bronchoscope contamination and to focus on implementing quality management systems to improve personnel competence, bronchoscope inventory management, maintenance, reprocessing effectiveness, and storage. In addition to following manufacturer's steps for reprocessing the devices, Ofstead et al. (2019) suggest the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities, which are currently available in the list of recommendations.

The applicant referenced a review article by Kovaleva et al.[23] in support of its claim that the Ambu® aScope™ 5 Broncho HD's single-use feature is free of biofilm from endoscope channels since routine cleaning procedures do not remove biofilm reliably from endoscope channels. This review presents an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopy and bronchoscopy and illustrates the impact of biofilm on endoscope reprocessing and post-endoscopic infection. Kovaleva et al. noted that the use of antibiofilm-oxidizing agents with an antimicrobial coating inside washer disinfectors could reduce biofilm build-up inside endoscopes and automated endoscope re-processors and decrease the risk of transmitting infections.[24] Per Kovaleva et al. while sterilization can be helpful to destroy microorganisms within biofilms, ethylene oxide sterilization may fail in the presence of organic debris after an inadequate cleaning procedure before reprocessing of flexible endoscopes. There was no mention of single-use bronchoscopes in the study.

The applicant cited a self-sponsored, laboratory study by Kurman et al.,[25] in general support of its application. Kurman et al. evaluated and assessed four different manufacturers' single-use flexible bronchoscopes (SFB), including the nominated device and its prior model, against their reusable flexible bronchoscopes (RFB) on a cadaver (*i.e.,* corpse) model, benchtop fixturing, and artificial plastic lung model. The study compared the Ambu® aScope™ 5 Broncho HD with four devices: (1) Olympus H-SteriScope; (2) Verathon BFLEX; (3) Boston Scientific Exalt-B; and (4) Ambu® aScope™ 4 Broncho (the prior model of the nominated device). The study concluded that the Ambu® aScope™ 5 Broncho HD has the highest overall performance, the highest overall rating for sampling, and highest maneuverability in difficult segmental airways among the comparator devices.

The applicant indicated that the Ambu® aScope™ 5 Broncho HD differs from these comparator devices as it is the only device that is compatible with argon gas plasma coagulation, cryotherapy, and laser, with an HD (1200x800) chip, has more degrees of articulation with tools, and provides image and video capture from the scope handle with multiple programmable functions including capture photo, start/end video, enable zoom, and initiate ARC. In addition, the applicant stated that the nominated device is superior to its earlier legally marketed device in terms of maneuverability into difficult segmental airways, overall performance, and overall sampling assessment. The applicant asserted that the nominated device differs from the predicate device due to a rotation mechanism on the handle and its superior articulation, which allow for more complicated procedures to be performed such as cryotherapy and coagulation. The applicant stated that the nominated device is equipped with an HD image chip and increased depth-of-field and field-of-view, which allow interventional pulmonologists to perform inspections, biopsies, and debulking. The applicant also stated that the nominated device's programmable buttons allow for superior documentation than the earlier bronchoscope device.

We note that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord and distal

37(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[20] Ofstead et al. acknowledged that this study was supported by an unrestricted research grant from Ambu Inc. The study sponsor did not participate in designing the study, identifying sites, collecting data, compiling results, interpreting the findings, or writing this article.

[21] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[22] Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest. 2018;154(5):1024–34.

[23] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clinical microbiology reviews, 26(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[24] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clinical microbiology reviews, 26(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[25] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

end, and insertion portion length. Furthermore, the 510(k) summary indicated that both have the same technical characteristics, which include maneuverable tip controlled by the user, flexible insertion cord, camera and LED light source at the distal tip, sterilized by ethylene oxide, single-use devices, ability for aspiration and sample collection in bronchoalveolar lavage, and bronchial wash procedures.

We note that in its application, the applicant provided a comparison of certain devices or device categories that it believed are most closely related or similar to the Ambu® aScope™ 5 Broncho HD. The applicant identified six reusable devices that it believed are most closely related: (1) Olympus Evis Exera Iii Bronchovideoscope Bf–h190; (2) Pentax EB–J10 Video Bronchoscope; (3) Fujifilm EB–580S Video Bronchoscope; (4) Olympus BF–Q190; (5) Olympus BF–1TH190; and (6) Olympus BF–XT190. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the Ambu® aScope™ 5 Broncho HD is used. The applicant stated that the Ambu® aScope™ 5 Broncho HD's single-use feature is unique among the comparators. According to the applicant, the single-use feature eliminates bronchoscope reprocessing. The applicant further submitted several articles reporting results on the prevalence of infection due to incomplete or inadequate processing for reusable bronchoscopes, which we summarize as follows. An article by Shimizu et al.[26] concluded that patients with larger lesions, presence of endobronchial lesions, histology of small-cell lung cancer, and advanced-disease stage tended to develop pulmonary infectious complications more often than other patients. A 2020 systematic literature review and meta-analysis by Travis et al.[27] reported an estimated average reusable FB cross-contamination rate of 8.69 percent ± 1.86 (standard division [SD]) (95 percent confidence interval [CI]: 5.06–12.33 percent) among eight studies from the U.S. and four European countries. Travis et al.[28] attributed the infection rate to the differences in the study design and sampling methods, geography, low number of data points, clinical settings, and an aversion towards publishing negative findings among the eight studies. Furthermore, the applicant submitted a 2019 systematic review and cost-effective analysis by Mouritsen et al.,[29] which reported an average 2.8 percent cross-contamination rate from reusable, flexible bronchoscopes among 16 studies from the United Kingdom, U.S., France, Spain, Australia, and Taiwan. Mouristen et al. identified that the single-use flexible bronchoscopes were cost effective and associated with a reduction of infection risk of approximately 1.71–4.07 percent compared with reusable flexible bronchoscopes. Lastly, the applicant again cited the meta study by Barron and Kennedy [30] referencing the findings from Ofstead et al.[31], the review by Mouristen et al., and the Emergency Care Research Institute's (ECRI's) report.[32] Of note, ECRI highlighted the recontamination of flexible endoscopes due to mishandling or improper storage as one of the top 10 health technology hazards.

Based on the evidence submitted with the application, we note the following concerns: We are concerned about whether the Ambu® aScope™ 5 Broncho HD can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Four of the studies the applicant submitted, Châteauvieux et al.,[33] Barron and Kennedy,[34] Kurman et al.,[35] and Ofstead et al.,[36] investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. In addition, we note that the studies provided also did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope in a clinical setting. In addition, we note that the applicant's self-sponsored study by Kurman, et al.[37] was conducted in the laboratory (*i.e.,* on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

Furthermore, we note that the Châteauvieux et al.[38] and Barron and Kennedy [39] studies suggested limiting the use of single-use bronchoscope device to specific situations (*i.e.,* after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting. We believe that further investigation with comparators in these specified cases would be particularly helpful to determine whether the device demonstrates substantial clinical improvements over currently available

[26] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[27] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[28] Id.

[29] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[30] Barron, S. P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[31] Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest. 2018;154(5):1024–34.

[32] ECRI. Top 10 health technology hazards. Executive brief. Pennsylvania: ECRI Institute, Health devices; 2019. p. 2019.

[33] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[34] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[35] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

[36] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[37] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

[38] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[39] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

treatments in the clinical setting where it is most likely to be used.

We note concern that the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable bronchoscope procedures, but do not directly show any clinical improvement that results from the use of the Ambu® aScope™ 5 Broncho HD. We note that Shimizu et al.,[40] Travis et al.,[41] Barron and Kennedy,[42] and Ofstead et al.[43] provided information about the risks associated with reprocessing reusable devices and reported mixed results.

We also note that the 2015 FDA safety notice[44] provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices in the notice. Furthermore, we note the following concerns about studies on the prevalence of infection due to incomplete/inadequate reprocessing of reusable bronchoscopes. The studies authored by Châteauvieux *et al.*,[45] Shimizu et al.,[46] Travis et al.,[47] and Mouritsen et al.[48] have small sample sizes. Furthermore, the Barron and Kennedy,[49] Travis et al.,[50] and Mouritsen et al.[51] studies used different study designs and sampling methodologies, or were performed in various clinical settings other than outpatient, which may affect the quality and reliability of the data provided in support of the applicant's assertions. We do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device. We are seeking comments on the prevalence of infection due to incomplete/inadequate processing for bronchoscopes in the U.S. and whether single-use bronchoscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

The applicant provided evidence which seemed to rely on indirect inferences from other sources of data. We question the relevance of the 2015 FDA safety notice[52] to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device. We are concerned that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection, providing studies with small sample sizes and other limitations as described above as their only support. We note that the applicant provided background information on the established reprocessing guidelines[53] for reusable devices; however, the existence of reprocessing guidelines does not provide evidence on the prevalence of infection rates, establish a relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available treatments.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ 5 Broncho HD would be reported with HCPCS codes listed in Table 31.

BILLING CODE 4120–01–P

[40] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. Nagoya journal of medical science, 82(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[41] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention, 17571774231158203.*

[42] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[43] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[44] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[45] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[46] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. Nagoya journal of medical science, 82(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[47] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention, 17571774231158203.*

[48] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[49] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[50] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. Journal of Infection Prevention, *17571774231158203.*

[51] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia*, 75(4), 529–540.

[52] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[53] FDA Guidance March 17, 2015, ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff.''

TABLE 31: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™ 5 BRONCHO HD

HCPCS Code	Long Descriptor	SI	APC
31615	Tracheobronchoscopy through established tracheostomy incision	T	5162
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing	J1	5153
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with brushing or protected brushings	J1	5153
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial alveolar lavage	J1	5153
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of fiducial markers, single or multiple	J1	5155
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), single lobe	J1	5154
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s). Trachea, main stem and/or lobar bronchus(i)	J1	5154
31630	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with tracheal/bronchial dilation or closed reduction of fracture	J1	5154
31631	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required	J1	5155
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	J1	5155
31635	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of foreign body	J1	5153
31636	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of bronchial stent(s)(includes tracheal/bronchial dilation as required), initial bronchus	J1	5155
31638	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)	J1	5155
31640	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with excision of tumor	J1	5154
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)	J1	5154

HCPCS Code	Long Descriptor	SI	APC
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of catheter(s) for intracavitary radioelement application	J1	5153
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, initial	J1	5153
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, subsequent, sams hospital stay	T	5152
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	J1	5155
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), initial lobe	J1	5154
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration(s)/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures	J1	5154
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration(s)/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures	J1	5154
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J1	5155
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J1	5155
31785	Excision of tracheal tumor or carcinoma; cervical	J1	5165
32400	Biopsy, pleura, percutaneous needle	J1	5072
32550	Insertion of indwelling tunneled pleural catheter with cuff	J1	5341
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	J1	5182
32552	Removal of indwelling tunneled pleural catheter with cuff	Q2	5181
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	T	5181
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with computer-assisted, image-guided navigation	**	N/A
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration	**	N/A

HCPCS Code	Long Descriptor	SI	APC
	biopsy(s), each additional lobe (list separately in addition to code for primary procedure)		
31637	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, each additional major bronchus stented (list separately in addition to code for primary procedure)	**	N/A
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)	**	N/A
31780	Excision tracheal stenosis and anastomosis; cervical	**	N/A
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	**	N/A
31786	Excision of tracheal tumor or carcinoma; thoracic	**	N/A
32200	Pneumonostomy, with open drainage of abscess or cyst	**	N/A
32674	Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)	**	N/A
32815	Open closure of major bronchial fistula	**	N/A

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060).

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To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5152, which had a CY 2022 payment rate of $383.33 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note that the HCPCS code 31646 identified by the applicant had a device offset amount of $0.00 at the time the application was received. Accordingly, we are evaluating the cost significance requirements using $0.00 as the appropriate device offset amount. According to the applicant, the cost of the Ambu® aScope™ 5 Broncho HD is $799.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD is 208.44 percent of the applicable APC payment amount for the service related to the category of devices of $383.33 (($799.00/$383.33) × 100 = 208.44 percent). Therefore, we believe the Ambu® aScope™ 5 Broncho HD meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). Given that there are no device-related costs in the APC payment amount, and the Ambu® aScope™ 5 Broncho HD has an estimated average reasonable cost of $799.00, we believe that the Ambu® aScope™ 5 Broncho HD meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $799.00 by 208.44 percent ((($799.00 − $0.00)/$383.33) × 100 = 208.44 percent). Therefore, we believe that the Ambu® aScope™ 5 Broncho HD meets the third cost significance requirement.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) Praxis Medical CytoCore

Praxis Medical, LLC submitted an application for a new device category for transitional pass-through payment status for Praxis Medical CytoCore (CytoCore) for CY 2024. Per the applicant, CytoCore is a single-use disposable biopsy instrument. Per the