

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

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ADVISORY PANEL ON HOSPITAL OUTPATIENT PAYMENT

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Monday, August 24, 2026

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The Advisory Panel convened at the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, and via Videoconference, at 9:48 a.m., Edith Hambrick, MD, JD, Chairperson, HOP Panel, presiding.

A P P E A R A N C E S

PANEL MEMBERS

JENNIFER ARTIGUE, RHIT, CCS
BECKY BEAN, BS, MHA/MBA, PharmD
NANCY DAWSON, MD, FACP
BLAKE DIRKSEN, MS, DABR
BRANDON FAZIO, BS
ADAM LEVIN, MD, MBA
SCOTT MANAKER, MD, PhD
DOUGLAS O'BRIEN
RAHUL SETH, DO, FASCO
WENDI SMITH LLOYD, CPC, COC, CPMA, COSC
WILLIAM TETTELBACH, MD, FACP, FIDSA, FUHM, MAPWCA,
CWSP
CAROLINE ZELLER, DDS, MPH

PRESIDING

EDITH HAMBRICK, MD, JD, Chairperson, HOP Panel

CMS STAFF

ABIGAIL CESNIK, Designated Federal Officer, Division
of Outpatient Care
KAREN MOHR, CMS
DON THOMPSON, Acting Director, Hospital and
Ambulatory Policy Group
DAVID RICE, Director, Division of Outpatient Care
ELISE BARRINGER, Division of Outpatient Care
NICOLE MARCOS, Division of Outpatient Care
GINA AUGHENBAUGH, Division of Outpatient Care
TONYA GIERKE, Division of Outpatient Care

CMS STAFF (Cont'd)

NATE VERCAUTEREN, Division of Outpatient Care

CORY DUKE, Division of Outpatient Care

GIL NGAN, Division of Outpatient Care

EDNA AYAH, Division of Outpatient Care

PRESENTERS AND PUBLIC COMMENTERS

GABRIEL BROWN, Director, Market Access, Pulmonx Corporation

STUART LANGBEIN, Partner, Hogan Lovells Cadwalader

MARSHALL BEDDER, MD, Chief Medical Officer, Neuralace Medical

JOE MILKOVITS, Neuralace Medical

BRANDON BENTZLEY, MD, PhD, Co-Founder and Chief Scientific Officer, Magnus Medical, Inc.

ERIC GREIG, Partner, Cooley LLP

MARCIA NUSGART, RPh, Founder and CEO, Alliance of Wound Care Stakeholders

KATHLEEN D. SCHAUM, MS, President, Kathleen D. Schaum and Associates, Inc.

GAYLE GORDILLO, MD, FACS, Senior Medical Director, UPMC Wound Healing Services

GREG O'GRADY, PhD, MD, FRACS, CEO, Alimetry

DANIEL KIM, MD, MBA, Inova Schar Cancer Institute

CRAIG WILKINSON, MD, VP, US Medical Affairs, Novocure

RUHY PATEL, Executive Director, Olympus Corporation

KRISTIN M. LA TERZA, CIC, COC, CPC, RPh, Manager, Health Economics and Market Access, Olympus Corporation of the Americas

SUSAN SLATON, Senior Director, US Health Policy and Reimbursement, Philips

PRESENTERS AND PUBLIC COMMENTERS (Cont'd)

DARSHAN DOSHI, MD, MS, Chief Medical Officer, Image-Guided Therapy Devices, Philips

TA-YUAN HO, Director, Health Economics & Market Access, Boston Scientific Corporation

CHANDRA N. BRANHAM, JD, Senior Director, US Policy, Medtech, Johnson & Johnson

ALEX WHITLEY, MD, PhD, FACRO, Central Alabama Radiation Oncology

MELISSA JOHNSON, Regional Director of Wound Care and Hyperbaric Services, Piedmont Healthcare

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1 P R O C E E D I N G S

2 (Whereupon, the meeting was called to
3 order at 9:48 a.m.)

4 DR. HAMBRICK: Good morning. My name is
5 Edith Hambrick, and I am the chairperson of the
6 Hospital Outpatient Payment Advisory Panel.

7 I would like to extend a hearty Centers
8 for Medicare and Medicaid Services welcome to the
9 2026 meeting of the Advisory Panel on Hospital
10 Outpatient Payment. With us today, through Teams, we
11 have presenters, commenters, and members of the
12 public. We welcome and look forward to your
13 presentations and comments.

14 First, I'd like the panel members to
15 introduce themselves. I would also like to say that
16 Dr. Adam Levin and Mr. Douglas O'Brien were sworn in
17 at the subcommittee meetings, but you'll hear more
18 about their backgrounds as we go forward.

19 So, if we could start in alphabetical
20 order. Ms. Artigue.

21 We're not hearing you.

22 MS. CESNIK: Ms. Artigue, I believe

1 you're muted. I believe you're still muted.

2 MS. MOHR: Ms. Artigue, please check the
3 device that you're speaking from. You may be double
4 muted.

5 DR. HAMBRICK: If not, I can start with
6 Dr. Zeller, reverse order. So, why don't we start
7 with Dr. Zeller and work our way through.

8 Oh, she's unmuted now.

9 MS. ARTIGUE: Hi, yes. Can you hear me
10 now?

11 MS. MOHR: Yes.

12 DR. HAMBRICK: Yes, we can.

13 MS. ARTIGUE: Yes, I'm sorry about that.

14 Hi, I'm Jennifer Artigue. I am with FMOL Health
15 based in Baton Rouge, Louisiana, with facilities in
16 Louisiana and Mississippi. I have oversight
17 responsibility in my role for HIM operations, coding,
18 and CDI, and this is my second year as a member of
19 the HOP Panel. So, thanks, looking forward to
20 today's presentation.

21 MS. BEAN: Hey, good morning, everybody.

22 My name is Becky Bean. I am the Senior Vice

1 President of Integrated Care Solutions for Novant
2 Health. We're a health system primarily in the North
3 Carolina, South Carolina area of the country.

4 I'm a pharmacist by background, but in my
5 role I support pharmacy, lab imaging, post-acute
6 rehab, and digital health. I think this is my third
7 year on the panel, and I will pass the baton to
8 Dr. Nancy Dawson.

9 DR. DAWSON: Thank you. I'm Dr. Nancy
10 Dawson. I'm an internal medicine hospitalist at Mayo
11 Clinic in Jacksonville, Florida, former chair of
12 hospital internal medicine as well as former chair of
13 the hospital, and this is my third year on the panel.

14 MR. DIRKSEN: Good morning, everyone. My
15 name is Blake Dirksen. I'm a clinical medical
16 physicist working in radiation oncology at the
17 University of Iowa, and this is my fourth year on the
18 panel.

19 MR. FAZIO: Hi, everyone. This is
20 Brandon Fazio, Senior Director of Finance for CHS in
21 their Ambulatory Surgery Center Division. This is
22 also my third year on the panel.

1 I'll turn it over to Dr. Levin.

2 DR. LEVIN: I'm Adam Levin. I'm an
3 orthopedic surgeon at Johns Hopkins Hospital,
4 surgical associate chief medical officer, and also
5 CPT advisor for the American Orthopedic Association.
6 This is my first year on the panel, and I'm happy to
7 be here.

8 Scott?

9 DR. MANAKER: There we go, now I'm
10 unmuted. I'm Scott Manaker. I'm a pulmonary and
11 critical care physician at the University of
12 Pennsylvania. I'm happy to be returning to the
13 hospital outpatient panel. I've been on it for a
14 number of years.

15 As I have done previously, I'll be
16 recusing myself from any votes directly related to
17 pulmonary and critical care medicine.

18 MR. O'BRIEN: Thank you. I'm Doug
19 O'Brien, Vice President of Corporate and Public
20 Affairs with Rush University System for Health in
21 Chicago. I come from more of a policy rather than
22 clinical background, done two tours of duty with HHS.

1 Also as deputy director of our state Medicaid agency,
2 and prior to taking over corporate and public affairs
3 at Rush, I was president of our clinically integrated
4 network and ACO at Rush.

5 And I am brand new to the panel and very
6 happy to be here. Thank you.

7 DR. SETH: My name is Rahul Seth. I am a
8 medical oncologist at Upstate Medical University in
9 Syracuse, New York. I am currently serving as the
10 last year of my subcommittee chair for the HOP Panel,
11 and I'm very glad to be participating in it.

12 MS. SMITH-LLOYD: Hi, I'm Wendi Smith-
13 Lloyd, an internal senior consultant in the HIM
14 coding and documentation excellence department at
15 Ochsner Health. Ochsner is a nonprofit, 46 hospital
16 health system serving Louisiana and the Gulf South
17 region. I've been with Ochsner for over seven and a
18 half years and have 35 years' experience in
19 healthcare management, revenue cycle, specializing in
20 pre-AR support with coding.

21 DR. ZELLER: I'll go ahead and go next.
22 I'm Caroline Zeller, happy to be here. I'm the

1 division head for the oral maxillofacial surgery and
2 hospital dentistry division in Oregon.

3 DR. HAMBRICK: Dr. Tettelbach is having a
4 little difficulty getting in, but I'm sure he'll join
5 us, and when he does, we'll acknowledge him too.

6 I'd like to acknowledge that Mr. Donald
7 Thompson, who we'll hear from later, he's the acting
8 director of the hospital and ambulatory policy group.

9 The final rule for the hospital inpatient
10 prospective payment system or IPPS for fiscal year
11 2027 was published in the federal register on August
12 4, 2026, 91 Federal Register 49570.

13 The notice of proposed rulemaking for the
14 hospital outpatient prospective payment system, or
15 OPPOS, ambulatory surgical centers, ASCs, for calendar
16 year 2027 was published in the federal register on
17 July 7, 2026, 91 Federal Register 41734. If you wish
18 to comment, comments must be submitted by August 31,
19 2026.

20 Notice of proposed rulemaking for the
21 Medicare physician fee schedule for calendar year
22 2027 was published in the federal register on July

1 16, 2026, 91 Federal Register 43842. If you wish to
2 comment, comments must be submitted by 5 p.m.,
3 September 14, 2026.

4 Now we'll discuss the charter for the
5 panel. The panel shall advise the secretary and the
6 administrator of CMS about the clinical integrity of
7 ambulatory payment classification, or APC groups, and
8 their associated weights. The panel is technical in
9 nature and it would deal with such issues as
10 addressing whether procedures are similar both
11 clinically and in terms of resource use, assigning
12 new current procedural technology, CPT, or HCPCS
13 codes to APCs, reassigning codes to different APCs,
14 reconfiguring the APCs into new APCs, evaluating the
15 required level of supervision for hospital outpatient
16 services, OPPS rates, or covered ASC procedures, et
17 cetera. The subject matter is limited to these and
18 related topics.

19 Unrelated topics are not subjects for
20 discussion. Unrelated topics include, but are not
21 limited to, the conversion factor, charge
22 compression, pass-through payments for medical

1 devices and drugs, wage adjustments, the types of
2 practitioners who are permitted to supervise
3 outpatient services, and the like. A copy of the
4 charter is available on the website with today's
5 materials.

6 The panel will hear presentations and
7 comments primarily related to the calendar year 2026
8 final rule and the calendar year 2027 notice of
9 proposed rulemaking. Comments that are not primarily
10 related to those rules may be ruled out of order.

11 Now let's walk through the two-times
12 rule. Section 1833(t)(2) of the Social Security Act
13 provides that, subject to certain exceptions, the
14 items and services within an APC group cannot be
15 considered comparable with respect to the use of
16 resources at the highest median or mean cost if
17 elected by the secretary or an item or service in the
18 group is more than two times greater than the lowest
19 median cost for an item or service within the same
20 group. This is referred to as the two-times rule.

21 In general, we use the geometric mean
22 cost of the item or service in implementing this

1 provision. The statute authorizes the secretary to
2 make exceptions to the two-times rule in unusual
3 cases such as low volume items and services.

4 The supporting documentation, there is a
5 two times listing. The two times data to which I
6 will be referring is the one using data as noted in
7 the proposed rule.

8 So let's walk through a couple of
9 examples. APC 5052, pages 18 to 19, there's no two
10 times violation. 97606 is the lowest significant
11 HCPCS code at \$295.89, page 18, and 36471 is the
12 highest significant HCPCS code at \$554.51 on page 19.
13 Hence, we do not have a two times violation.

14 If you look at APC 5071, however, on
15 pages 25 to 26, there is a two times violation.
16 19000 is the lowest significant HCPCS code at \$538.85
17 on page 25 and 19283 is the HCPCS code with the
18 highest significant cost at \$1085.14. That's on page
19 26.

20 Oral presentations should not exceed five
21 minutes in length for any individual or organization.
22 The chair may further limit time allowed for

1 presentations due to the number of oral presentations
2 if necessary.

3 In addition to formal oral presentations,
4 there will be an opportunity during the meeting for
5 public oral comments that will be limited to one
6 minute for each individual and a total of three
7 minutes per organization.

8 Please queue up as instructed by our
9 moderator, Ms. Karen Mohr, if you wish to address the
10 panel. Please clearly identify yourself and your
11 organization, if applicable, before speaking.

12 Are there any questions before we get
13 started?

14 We'll now hear from Mr. Donald Thompson,
15 after which a few housekeeping details will be
16 discussed by Ms. Abigail Cesnik, the designated
17 federal official for the panel.

18 MR. THOMPSON: Thank you, Dr. Hambrick.
19 Good morning, everyone. I'm Don Thompson, and as
20 Dr. Hambrick said, I'm the acting director of the
21 Hospital Ambulatory Policy Group. Pleased to
22 virtually welcome all of you to the 2026 meeting of

1 the advisory panel. This is the 39th meeting of the
2 panel since its inception in 2001. As always, we
3 appreciate the panel's expertise, and we value its
4 contributions to improve CMS policy by strengthening
5 the connection between Medicare payments and patient-
6 centered efficient care for our beneficiaries.

7 Shortly, David Rice, who is the director
8 of the Division of Outpatient Care, will provide a
9 policy overview of both last year's OPPS ASC final
10 rule, as well as the recently published proposed
11 rule, which is still in its public comment period.

12 I'd like to say a few words about the HOP
13 Panel. We've long recognized the importance of the
14 public's role in developing effective policies, and
15 we count on the assistance of the advisory panel for
16 its diverse perspectives and expertise.

17 Additionally, advisory committees such as
18 this ensure that the public involvement and
19 transparency are part of the federal policymaking
20 process. This specific panel is charged with
21 advising the Secretary and the Administrator on the
22 clinical integrity of the APC groups and their

1 associated group weights for the OPPS.

2 And with the renewal of the panel charter
3 in November of 2018, the panel may, in their
4 deliberation of OPPS payment rates, also consider
5 that covered procedures within the ASC payment system
6 are, in fact, impacted by the OPPS APC groups and
7 their associated weights.

8 The fundamental components of the OPPS
9 have had significant impact and effect on CMS's
10 ability to support beneficiary choice, lower
11 beneficiary costs, and promote high-quality and
12 efficient hospital outpatient services. We greatly
13 value the panel's recommendations on this important
14 payment system.

15 At this time, I'd also like to personally
16 thank and recognize all the members of the panel for
17 contributing their time and expertise. And as
18 mentioned, there are two new members, and extend a
19 warm welcome to them, Dr. Adam Levin and Douglas
20 O'Brien, as was talked about earlier.

21 We're always looking for new panel
22 members, and I invite you to nominate yourself or

1 someone you think would be a great asset to the HOP
2 Panel moving forward.

3 Finally, we hope you'll take advantage of
4 this opportunity to discuss and engage with the
5 issues before the panel. I encourage everyone to
6 share your feedback in the form of written public
7 comments to the proposed rule by the September 15th
8 deadline. You can submit early. You don't have to
9 wait until the last second, but the deadline is
10 September 15th, so that your important feedback can
11 be considered in the development of the final rule.

12 I look forward to this year's
13 discussions, and with that, I will turn it over to
14 Abby for technical meeting reminders. Thank you.

15 MS. CESNIK: Hi, everyone. Thank you.
16 Thank you, Don.

17 Good morning. I'm Abby Cesnik, the
18 Designated Federal Officer for this year's HOP Panel
19 meeting. Welcome. We're happy to have you here
20 today virtually.

21 I'd like to go over some brief technical
22 reminders. First, to presenters and HOP Panel

1 members, please remember to stay on mute when you're
2 not speaking. When we get to portions of the meeting
3 where the public can make comments or ask questions,
4 please use the raise hand feature in Teams, or you
5 can also type a question into the chat.

6 If you are a presenter, welcome. We look
7 forward to hearing your presentation. Please cue us
8 when you are ready for the next slide so we can
9 advance them for you. You're welcome to turn on your
10 camera during the presentation, but please turn it
11 off when you're not speaking.

12 To allow the audience to view your camera
13 during the presentation, you can press the toggle
14 button on the top right of your picture to be moved
15 into the public viewing area.

16 For presenters who had to register as
17 attendees, as a reminder, a moderator will promote
18 you to a presenter role when it is time for your
19 presentation. Please make sure to accept the prompt
20 in order to be moved to the presenter role.

21 Due to a limit on the number of external
22 presenters we can have at one time, presenters who

1 have already presented may be moved into attendee
2 status to allow later presenters to move to the
3 presenter role.

4 You will have five minutes for your
5 presentation. One of our team members will cue you
6 when you have one minute remaining and when you have
7 reached the end of your time.

8 We'd like to remind everyone that this
9 meeting and the chat box in Teams are both being
10 recorded.

11 Finally, if you need Teams technical
12 assistance, please write to us using the chat feature
13 on Teams or send an email to our Teams moderator,
14 Karen Mohr. If you have other questions related to
15 the meeting, please email the APC panel mailbox. We
16 will be including both email addresses in the chat.

17 And thanks everyone for joining us today,
18 and I will now turn it over to David Rice. Thank
19 you.

20 MR. RICE: Hi, everyone. I'm David Rice,
21 the Director of the Division of Outpatient Care, and
22 I'll be giving a brief overview of the two OPPS rules

1 that have been published since the last HOP Panel
2 meeting in August of 2025.

3 First, I'd like to acknowledge all the
4 folks in the Division of Outpatient Care whose hard
5 work allows us to host this meeting. You'll see
6 their names listed on the slide, and you'll be
7 hearing from many of them today during our
8 presentations.

9 I'd also like to note that the OPSS is a
10 prospective payment system and not a fee schedule,
11 and that all items and services paid under the OPSS
12 are paid based on a grouping of items and services
13 that have similar costs and that are clinically
14 similar.

15 The calendar year 2026 OPSS ASC Final
16 Rule displayed on November 21, 2025, and I'll mention
17 a few brief OPSS and ASE items that were included in
18 this rule.

19 The next slide. The -- in accordance
20 with statutory requirements, CMS finalized an update
21 to the OPSS payment rates for hospitals that meet
22 applicable quality reporting requirements by 2.6

1 percent. This update was based on the hospital
2 market basket percentage increase of 3.3 percent,
3 reduced by a 0.7 percentage point productivity
4 adjustment.

5 For calendar year 2026, using the
6 hospital market basket update, CMS also finalized an
7 update factor to the ASC rates of 2.6 percent.

8 In the 2019 OPPS ASC Final Rule, CMS
9 adopted a policy to control unnecessary increases in
10 the volume of clinic visit services furnished in
11 accepted off-campus provider-based departments. This
12 method prevents Medicare beneficiaries from paying
13 significantly more in the accepted off-campus
14 provider-based setting than in the physician office
15 setting.

16 For 2026, CMS finalized its proposal to
17 expand this policy to include drug administration
18 services furnished in accepted off-campus provider-
19 based departments.

20 Specifically, CMS used the agency's
21 authority under Section 1833(t)(2)(f) of the Social
22 Security Act to apply the physician fee schedule

1 equivalent payment rate for any codes that are
2 assigned to drug administration ambulatory payment
3 classifications when provided at off-campus provider-
4 based departments.

5 For 2026, we estimated that this
6 provision would reduce OPPS spending by \$290 million,
7 with \$220 million of the savings accruing to Medicare
8 and \$70 million saved by Medicare beneficiaries in
9 the form of reduced coinsurance.

10 Moving to the next slide. We also
11 finalized a proposal to phase out the inpatient only
12 list over a three-year period, beginning with removal
13 of 285 mostly musculoskeletal procedures for calendar
14 year 2026. This policy allows for these services to
15 be paid in the -- by Medicare in the hospital
16 outpatient setting when determined to be clinically
17 appropriate, giving physicians greater flexibility in
18 determining the most appropriate site of service.

19 For 2026, CMS also finalized its proposal
20 to revise the ASC covered procedures list criteria to
21 modify the general standard criteria and eliminate
22 five of the general exclusion criteria, moving them

1 into a new section as non-binding physician
2 considerations for patient safety.

3 As a result of these criteria changes,
4 CMS added 289 procedures to the ASC covered
5 procedures list. Additionally, CMS added 271 codes
6 to the ASC covered procedures list that were removed
7 from the inpatient only list for 2026.

8 Moving to the next slide. Since calendar
9 year 2014, CMS has unconditionally packaged skin
10 substitute products furnished in outpatient hospital
11 settings into their associated application procedures
12 as part of a broader policy to package all drugs and
13 biologicals that function as supplies when used in a
14 surgical procedure.

15 For 2026, CMS finalized its proposal to
16 unpackage skin substitute products from the
17 application services and establish several APCs based
18 on the relevant product characteristics rather than
19 based on stated prices for the provision of these
20 products when they are used during a covered
21 application procedure paid under the OPFS.

22 CMS also aligned skin substitute

1 categorization for payment purposes, consistent with
2 FDA regulatory status for 361 human cells, tissues,
3 and cellular and tissue-based products, and the
4 device types, pre-market approval, and 510ks.

5 For 2026, CMS used a single payment rate
6 for these three categories of skin substitute
7 products to ensure we are not underestimating the
8 resources involved with furnishing these services.
9 CMS finalized proposals to implement these policy
10 changes in both the hospital outpatient and physician
11 office settings to remain consistent across different
12 settings of care.

13 Moving to the next slide. The calendar
14 year 2027 OPPS ASC proposed rule displayed on July 2,
15 2026. The comment period closes next week on August
16 31st. I just want to emphasize that because I think
17 an incorrect date was mentioned earlier. The comment
18 period for the OPPS rule closes on August 31st, one
19 week from today, so please make sure to get your
20 comments in by August 31st.

21 And the final rule is targeted for
22 display on November 1st. I'll mention a few brief

1 OPPS and ASC items that were included in this rule.

2 First, for the rate updates, CMS is
3 proposing to update the OPPS payment rates for
4 hospitals that meet applicable quality reporting
5 requirements by 2.4 percent. This update is based on
6 the projected hospital market basket percentage
7 increase of 3.2 percent, reduced by 0.8 percentage
8 points for productivity.

9 CMS is also proposing to update the ASC
10 payment rates by 2.4 percent using the same
11 productivity-adjusted market basket update that was
12 used to update the OPPS rates.

13 For 2027, CMS is proposing to include
14 imaging without contrast services furnished in
15 accepted off-campus provider-based departments under
16 the volume control method. Specifically, CMS is
17 proposing to use the agency's authority under Section
18 1833(t)(2)(f) to apply the physician fee schedule
19 equivalent payment rate for any codes assigned to
20 imaging without contrast ambulatory payment
21 classifications when provided at an off-campus
22 provider-based department accepted from Section 603

1 of the Bipartisan Budget Act of 2015.

2 As with the existing volume control
3 method for off-campus clinic visits and drug
4 administration services, CMS is proposing to exempt
5 rural sole community hospitals from this proposed
6 policy.

7 For 2027, we estimate that this provision
8 would reduce Medicare Part B expenditures by
9 approximately \$260 million in the first year,
10 including approximately \$190 million in Part B
11 savings and approximately \$70 million in reduced
12 beneficiary co-insurance. In addition, beneficiary
13 premiums are estimated to decrease by approximately
14 \$70 million. This policy helps to ensure that
15 beneficiaries are not subject to higher premiums and
16 cost sharing based solely on the site at which the
17 care is furnished.

18 Moving to the next slide. For 2027, the
19 second year of the inpatient-only list phase-out, CMS
20 is proposing to remove 638 services from 14 clinical
21 families. This proposal would allow for these
22 services to be paid by Medicare in the hospital

1 outpatient setting when determined to be clinically
2 appropriate.

3 Moving to the reduced payment for 340B
4 acquired drugs policy. Section 1833(t)(14)(d2) of
5 the Social Security Act requires the Secretary to
6 periodically conduct hospital drug acquisition cost
7 surveys for specified covered outpatient drugs and
8 use this information to set the payment rates for
9 these drugs.

10 Accordingly, from January 1, 2026,
11 through April 7, 2026, we conducted a survey of the
12 acquisition costs for each separately payable drug
13 acquired by all hospitals paid under the OPPS. The
14 survey revealed significant disparities between
15 hospital acquisition costs for drugs acquired through
16 the 340B program and those drugs acquired outside of
17 the 340B program.

18 Taking the survey's results into account
19 to more accurately align Medicare payments with
20 hospital drug acquisition costs, we are proposing for
21 calendar year 2027 to pay for 340B acquired drugs at
22 the drug's average sales price minus 33.4 percent.

1 This proposal is estimated to reduce original
2 Medicare drug payment by \$4.55 billion and
3 beneficiary drug payment by \$1.15 billion in the
4 first year.

5 The statute requires that this policy be
6 implemented in a budget-neutral manner, and so this
7 policy would be -- would increase OPPS payments for
8 non-drug services by an equivalent amount.

9 Moving to the next slide. The November
10 2023 340B remedy final rule finalized the changes to
11 the calculation of the OPPS conversion factor
12 applicable to non-drug items and services beginning
13 in 2026. Specifically, the rule codified a half-
14 percentage point reduction in the OPPS conversion
15 factor to non-drug items and services, excluding
16 hospitals that enrolled in Medicare after January 1,
17 2018.

18 This reduction would remain in effect
19 until the estimated aggregate payment reduction
20 reached the \$7.8 billion of increased non-drug items
21 and services payments made from calendar year 2018
22 through 2022. This prospective offset aimed to

1 balance the goal of restoring hospitals to their
2 financial position had the original 340B policy not
3 existed while avoiding burdening them with an
4 immediate single-year recovery.

5 After subsequent reconsideration of
6 balancing these two goals, CMS has determined that a
7 shorter time frame is more appropriate.

8 Consequently, CMS is proposing to revise the annual
9 offset percentage for non-drug items and services
10 from half a percent to 3 percent effective calendar
11 year 2027. This 3 percent reduction would remain in
12 effect until the estimated payment reduction reaches
13 \$7.8 billion, which CMS estimates will occur in
14 calendar year 2029.

15 And now I will pass the meeting back to
16 Dr. Hambrick.

17 DR. HAMBRICK: Thank you, Mr. Rice.

18 Now we're going to have our subcommittee
19 reports. The first one is for the Ambulatory Payment
20 Classification Group and Status Indicator
21 Subcommittee, and Dr. Raul Seth will give us that
22 report.

1 DR. SETH: Good morning. Thank you guys
2 all for participating in this meeting. I am the
3 subcommittee chair for the Ambulatory Payment
4 Classification Group and the Status Indicator
5 Subcommittee Report.

6 At this time, the committee was able to
7 meet on August 14, 2026, and we did review our
8 proposed and we had discussion. Panel comments were
9 very lively and appropriate for discussion of the
10 presentations that we have had. And at this time,
11 there was no other conflicts. Everybody was able to
12 participate and discuss freely. And I want to say
13 thank you to everybody who helped out.

14 DR. HAMBRICK: Thank you. Are there any
15 questions for Dr. Seth?

16 I entertain a motion to accept the
17 minutes from the subcommittee meeting.

18 DR. SETH: Sorry. I just want to add,
19 this is my last meeting as the chair. We have
20 elected Dr. Adam Levin to take over, and I
21 congratulate him.

22 DR. MANAKER: I move we accept the

1 committee report, Dr. Hambrick.

2 DR. HAMBRICK: Thank you.

3 DR. SETH: Thank you, Scott.

4 DR. HAMBRICK: Is there a second?

5 DR. LEVIN: Second.

6 DR. HAMBRICK: Discussion? All those in
7 favor of accepting the report, please indicate by
8 saying "aye."

9 (Simultaneous "ayes")

10 DR. HAMBRICK: Opposed, nay.

11 Abstentions?

12 Thank you. The report is accepted.

13 Next, we'll hear from the Data
14 Subcommittee. Dr. Tettelbach will present that
15 report.

16 DR. TETTELACH: Yes, hello. I just
17 needed to turn everything on here.

18 So, again, I want to express my gratitude
19 for all that were involved in the August 19th meeting
20 of the Data Subcommittee. Again, there were no
21 conflicts of interest that were noted during this
22 meeting.

1 The Data Subcommittee reviewed CMS's
2 claims accounting process used to develop the
3 calendar year 2027 OPPS proposed payment rates, the
4 APC with greater than 10% changes in geometric mean
5 cost between calendar year 2026 final rule and the
6 calendar year 2027 proposed rule, and CMS's data
7 process for comprehensive APC complexity adjustments.

8 We did not make a recommendation on
9 changes to the complexity adjustment methodology and
10 deferred that to the full HOP Panel. The
11 Subcommittee voted to continue receiving two data
12 resources next year, the claims accounting overview
13 for CY 2028 OPPS NPRM and file identifying APCs with
14 greater than 10% fluctuation in geometric mean cost
15 between CY 2027 OPPS final rule and the CY 2028 OPPS
16 NPRM.

17 These data help panel identify
18 significant year-to-year changes and determine where
19 additional review may be needed. These were the
20 recommendations of the Data Subcommittee.

21 Also, I -- this is my last time as chair
22 of the Data Subcommittee, and Jennifer Artigue was

1 elected or proposed to serve as the 2027 chair of the
2 Data Subcommittee. And I welcome -- you know,
3 comments are welcome, and we hand this back over.
4 Thank you very much.

5 DR. HAMBRICK: Thank you. Any comments
6 or questions for Dr. Tettelbach or anybody on the
7 Data Subcommittee?

8 If not, I'll entertain a motion to accept
9 the... Move to accept the minutes.

10 MR. O'BRIEN: Move to accept.

11 MS. BEAN: Second.

12 DR. SETH: Second.

13 DR. MANAKER: Second.

14 DR. HAMBRICK: Discussion?

15 All those in favor say "aye."

16 (Simultaneous "ayes")

17 DR. HAMBRICK: Opposed, nay.

18 Any abstentions? Great. So, the motion
19 passed.

20 I see that we're scheduled for a break.
21 We're ahead of schedule. Let's keep it that way.
22 So, I'll see everybody back at 10:16 unless you want

1 -- no.

2 Okay. So, 10 -- be back at 10:16. Thank
3 you.

4 (Session is in recess at 10:11 a.m.)

5

6 (Session resumes at 10:16 a.m.)

7 DR. HAMBRICK: Good morning again. This
8 is Edith Hambrick. We're now going to hear some
9 presentations about comprehensive APC complexity
10 adjustments. Elise Barringer from the Outpatient
11 Care Division will speak first, followed by
12 presentations, Susan Slaton and Dr. Darshan Doshi of
13 Philips, Ta-Yuan Ho from Boston Scientific, and
14 Chandra Branham from Johnson & Johnson, in that
15 order.

16 I'm just slowing a little bit so
17 everybody can get in order and so if people need to
18 be promoted, they can get promoted.

19 Okay, Ms. Barringer, why don't you go
20 ahead.

21 MS. BARRINGER: Thank you, Dr. Hambrick.

22 Good morning. I'll be covering the

1 overview for the Boston Scientific, Johnson &
2 Johnson, and Philips presentations on the
3 comprehensive APC or CAPC complexity adjustment
4 methodology.

5 CAPCs provide a single payment for a
6 primary service identified by status indicator J1
7 packaging payment for adjunctive and secondary items,
8 services, and procedures into the most costly primary
9 procedure on a claim. Complexity adjustments are
10 used to provide increased payment for certain
11 comprehensive services.

12 We apply complexity adjustments by
13 promoting qualifying paired J1 service code
14 combinations or paired code combinations of J1
15 services and certain add-on codes from the
16 originating CAPC to the next higher-paying CAPC in
17 the same clinical family of APCs.

18 The criteria for a complexity adjustment
19 are that a paired code combination represents a
20 complex, costly form or version of the primary
21 service by meeting, one, a frequency threshold of 25
22 or more claims reporting the code combination, and

1 two, a cost threshold where the geometric mean cost
2 of all evaluated claims is a violation of the two-
3 times rule in the originating CAPC.

4 For new HCPCS codes, we determine initial
5 CAPC assignment and qualifications for complexity
6 adjustment using the best available information,
7 crosswalking the new HCPCS codes to a predecessor
8 code or codes when appropriate.

9 Our proposed and final list of complexity
10 adjustments, as well as all combinations that were
11 evaluated, are provided in Addendum J to our proposed
12 and final rules. In the calendar year 2027 OPPS ASC
13 rule, we propose to maintain our current CAPC
14 methodology.

15 Boston Scientific and Johnson & Johnson
16 recommend that CMS revise the cost threshold for
17 determining whether a code combination qualifies for
18 a complexity adjustment. Specifically, they
19 recommend using the lower of either the current two-
20 times rule threshold or the geometric mean cost of
21 the lowest cost-significant procedure assigned to the
22 next higher-paying CAPC.

1 Philips recommends that CMS use
2 predecessor codes' claims history when evaluating the
3 next -- evaluating the new lower extremity
4 revascularization codes for calendar year 2027
5 complexity adjustment eligibility. Specifically,
6 Philips recommends that CMS crosswalk the new codes
7 to the appropriate predecessor CPT HCPCS codes and
8 preserve complexity adjustments for code combinations
9 that previously met CMS's applicable frequency and
10 cost criteria.

11 This concludes my presentation.

12 DR. HAMBRICK: Thank you. First, we'll
13 hear from Susan Slaton and Dr. Darshan Doshi from
14 Philips. And for those following along in their two-
15 times rule, APC 5192 is on pages 99 to 100 and APC
16 5193 on pages 100 to 101.

17 Philips, you may go ahead.

18 MS. SLATON: Thank you. Thank you.

19 Good morning and thank you for the
20 opportunity to speak with the HOP Panel today. I am
21 Susan Slaton, and with me is my colleague,
22 Dr. Darshan Doshi.

1 We're here today to ask the HOP Panel to
2 recommend that CMS use the predecessor code claims
3 history to evaluate the calendar year '27 complexity
4 adjustment eligibility for the lower extremity
5 revascularization codes consistent with the
6 methodology CMS used in 2026.

7 This slide is intended as an upfront
8 summary for the panel. Rather than walk through it
9 line by line, I'm going to move to the next slides,
10 which explain the concern and our recommendation in
11 more detail.

12 So, effective January 1, 2026, 16
13 predecessor codes were replaced by a more granular
14 code set of more than 40 new or revised CPT codes,
15 making predecessor to new code walk crossing more
16 complex, particularly when there is not a one-to-one
17 match.

18 Next slide, please. However, in calendar
19 year 2026, CMS used the predecessor code crosswalks
20 for both APC assignment and complexity adjustment
21 evaluation.

22 Next slide, please. This slide

1 illustrates the core issue, but it's not the only
2 example. In the calendar year 2027 OPPS proposed
3 rule, CMS used predecessor code data to establish APC
4 placement, but did not apply the same methodology to
5 complexity adjustment eligibility as they did in
6 2026. Although these predecessor combinations are
7 proposed to be eligible for complexity adjustments in
8 calendar year 2027, hospitals can no longer report
9 them, effectively eliminating all complexity
10 adjustments recognition under the current code
11 structure.

12 Next slide, please. This is one example
13 of why this matters. Without complexity adjustments,
14 hospitals may be significantly underpaid for the
15 resources required. Multi-level disease is common in
16 that one-third or more patients have disease across
17 multiple territories that can be treated at the same
18 episode of care.

19 In this example, a beneficiary is treated
20 for a vascular disease in both the femoral and the
21 iliac territories. As shown in the top chart, when
22 these two procedures are provided at the same

1 encounter, CMS calculated a geometric mean cost of
2 about \$12,600.

3 The second table illustrates the impact
4 if complexity adjustments are not evaluated
5 appropriately. In this example, a predecessor code
6 37224 crosswalks to 37263 or 37265 and are assigned
7 to comprehensive APC 5192 with the proposed payment
8 of about \$6,700.

9 Because many of the new LAR codes have J1
10 status indicators and are eligible for complexity
11 adjustments, when multi-level disease is treated, the
12 secondary procedure is packaged. That leaves roughly
13 a \$5,900 difference relative to CMS's documented cost
14 of furnishing the combined service and shows how a
15 coding transition can materially affect payment when
16 a complexity adjustment is no longer recognized.

17 Next slide, please. In summary, because
18 clinically significant disease may involve more than
19 one vascular territory, combinations of the LAR codes
20 reflect established patterns of care. So,
21 predecessor code data can provide reliable cost
22 information when new CPT codes do not yet have

1 sufficient claims experience.

2 Therefore, we are again asking the panel
3 to recommend that CMS use the same predecessor code
4 crosswalk methodology for the calendar year 2027
5 complexity adjustment evaluation. We also ask the
6 same predecessor codes claim history is used when
7 evaluating complexity adjustments in the ASC setting.

8 The use of predecessor code data is an
9 appropriate interim approach --

10 MS. AUGHENBAUGH: Excuse me. This is
11 your one-minute reminder.

12 MS. SLATON: Okay.

13 -- interim approach until sufficient cost
14 data for the new codes that are available for
15 calendar year 2028 rate setting.

16 In closing, we believe this approach is
17 consistent with CMS policy, supports payment
18 accuracy, and helps maintain beneficiary access to
19 complex revascularization services.

20 We appreciate the panel's consideration
21 of this request, and I want to thank you for your
22 time today.

1 DR. HAMBRICK: I think we'll wait for all
2 the questions until the end until we hear all the
3 presentations.

4 So next we're going to hear from Boston
5 Scientific from Ta-Yuan Ho.

6 MR. HO: Thank you for your time and
7 attention today. My name is Ta-Yuan Ho, Director of
8 Health Economics and Market Access for Boston
9 Scientific.

10 Next slide, please. The current cost
11 threshold methodology uses the two-times rule. This
12 often works well for lower cost APCs, but becomes
13 problematic for higher cost APCs and those with wider
14 cost spans.

15 We believe that the complexity adjustment
16 policy, which was first implemented over a decade ago
17 to provide appropriate payment for complex subsets of
18 the primary procedure, has not kept pace with
19 advancements in clinical practice and needs to be
20 modernized. Without refinements to this policy,
21 financial disincentives to providing guideline-
22 recommended care may persist, and so we request that

1 CMS revise the cost threshold to utilize the lower of
2 either the two-times rule or the geometric mean cost
3 of the lowest cost significant procedure in the next
4 higher APC.

5 Next slide, please. Lower cost APCs
6 often have costs in the hundreds or even thousands of
7 dollars. However, for higher cost APCs, which often
8 have costs in the tens of thousands of dollars, using
9 the two-times rule doesn't work well.

10 There are real dollar differences from
11 \$500 to \$1,000 that are not the same as from \$5,000
12 to \$10,000, or even more so from \$10,000 to \$20,000.

13 But today, the two-times rule is applied uniformly
14 for all APCs without consideration for these real
15 dollar differences.

16 We propose a more flexible cost threshold
17 methodology that for each APC would run a
18 straightforward objective test and use the lower of
19 these two criteria. This method would increase the
20 number of co-combinations that would qualify for a
21 adjustment, enabling appropriate payment for these
22 complex procedures. We also anticipate that it may

1 stabilize payment for co-pairs year over year.

2 Next slide, please. I'd like to point
3 your attention to the musculoskeletal APCs, which
4 just last year added a new top level seven as part of
5 CMS's effort to remove procedures from the inpatient
6 only list. For levels two, three, and four, the two-
7 times rule shown in red seems to work pretty well.
8 But for levels five and six, the threshold is
9 thousands of dollars greater than any significant
10 procedures in the next higher APC.

11 A similar trend holds true in the
12 endovascular APCs where for levels one and two the
13 current cost threshold looks reasonable. But once
14 again, for the higher cost APC, level three, the two-
15 times rule breaks down and it is thousands of dollars
16 greater than many other procedures established in
17 level four.

18 For higher cost APCs, the magnitude of
19 the difference between the cost threshold methodology
20 shown in red and green is both clear and significant.

21 Next slide, please. I'd like to
22 highlight a specific clinical example, multivessel

1 PCI. Multivessel coronary artery disease is a common
2 condition and for STEMI patients, which is one of the
3 most severe presentations, a complete
4 revascularization strategy carries a level 1A
5 clinical guideline recommendation.

6 The guidelines state that the complete
7 revasc can be done either at the time of primary PCI
8 as an inpatient or as a staged procedure, which is
9 typically outpatient.

10 Currently, PCI for STEMI is on the IPO
11 list, but CMS will be removing it for 2028. And so
12 establishing appropriate payment for multivessel PCI
13 is very important.

14 Treatment for patients such as NSTEMI and
15 stable angina also follow the same complete revasc
16 strategy and often receive multivessel PCI, many of
17 which are performed on an outpatient basis today.

18 There's also some coding nuance here.
19 Outpatient PCI is reported on a per vessel basis
20 using primary J1 codes with five major coronary
21 artery modifiers. Multivessel PCI can be reported
22 with separate primary J1 codes or multiple units of

1 the same J1 code. Because of this unique coding
2 convention, appropriate payment for multivessel PCI
3 is only possible through the complexity adjustment
4 policy.

5 Next slide, please. Multivessel DES PCI
6 is the most common combination performed. And for
7 the past decade, the combination has had an average
8 frequency of over 10,000 procedures. Most recently,
9 this combination was 11% of all DES PCI, which is the
10 most common type of PCI.

11 In fact, if we compare the frequency of
12 just this specific combination to any single
13 individual J1 procedure in the next higher level APC,
14 level 4, it would be the highest frequency by over
15 4000 procedures. When we analyze the cost,
16 multivessel DES PCI averages 50% greater cost than
17 single vessel. And yet, qualification for complexity
18 adjustment has been inconsistent with the current
19 cost threshold.

20 If you look at the trend on the right,
21 you can see that the cost difference has held steady
22 for the entire decade. If we historically applied

1 our proposed cost threshold method, this combination
2 would have qualified every single year.

3 MS. AUGHENBAUGH: One minute remaining.

4 MR. HO: For the years when this
5 combination did not qualify -- thank you.

6 For the years when this combination did
7 not qualify for complexity adjustment, hospitals have
8 continued to provide this guideline-directed medical
9 care while having to absorb these substantial costs.

10 It is for these reasons that we request
11 that CMS revise the cost threshold to allow a more
12 flexible approach. Thank you for your time.

13 DR. HAMBRICK: Thank you.

14 And for those who want to know where
15 C9600 is, it's APC 5193. It's on page 100.

16 Next, we'll hear from Ms. Chandra Branham
17 from Johnson & Johnson.

18 And some of the codes, I'll tell you
19 where you can find them on the two time rules. APC
20 5192 is on pages 99 to 100. APC 5191, page 99. APC
21 5232, pages 107 to 108. And APC 5231, page 107.

22 All right, Ms. Branham.

1 MS. BRANHAM: Hi, good morning. Chandra
2 Branham from Johnson & Johnson. Let me see if I can
3 turn my camera on. Chandra Branham from Johnson &
4 Johnson.

5 If we could go to the next slide. I just
6 have a very brief presentation that I believe is very
7 complementary to Boston Scientific's presentation
8 that you just heard. I'm going to focus on
9 application of the two-times rule for the complexity
10 adjustment and why we believe that the current two-
11 times rule provides inconsistent outcomes at the
12 lower cost and higher cost ranges of the APC.

13 So, if we could go to the next slide,
14 please. This is just a restatement of where we see
15 the issue. We are definitely seeing a gap in the way
16 complexity adjustments are applied when there are
17 new, innovative, higher resource technologies
18 introduced, and this is creating an operational risk
19 for hospitals. They may risk financial loss when
20 they provide these high-cost procedure combinations
21 that are -- that remain assigned to lower-cost APCs.

22 So, we believe, like the previous

1 presentation, that there are modifications that could
2 be made to the underlying system to offset some of
3 those hospital costs for adopting new technologies,
4 protect hospitals, and also result in appropriate
5 payment for those costly and complex code
6 combinations.

7 And the last note is just that last year
8 CMS did issue an RFI on this topic and received, you
9 know, robust comments from stakeholders, but did not
10 propose any changes in this year's OPPS proposed
11 rule.

12 So, the next slide, please. So, I have a
13 bit more simplified couple of examples just to show
14 how the two-times rule, we believe, really kind of
15 breaks down at the higher APC cost levels.

16 So, if you see on the left, you've got a
17 lower-cost APC structure. We're looking at
18 endovascular level 2. To get into endovascular level
19 2 from level 1, the two-times threshold falls
20 squarely in the middle of level 2. The two-times
21 rule is achievable, and the more costly code
22 combinations that are more fitting in the higher-cost

1 APC can be promoted to that APC, where at the higher
2 level, there's an example of ICD level 2 with a
3 payment of \$35,000. To be promoted from level 1 to
4 level 2, the cost threshold generated by the two-
5 times rule is \$44,400, which, as you can see, it
6 exceeds the cost of any of the significant procedures
7 in level 2.

8 So, it results in an unachievable and
9 somewhat nonsensical outcome of needing to reach a
10 threshold that is so significantly higher than even
11 the highest-cost procedures in that APC. So, we see
12 this breakdown.

13 So, if we could go to the next slide.
14 So, and the final slide, which we'll get to, is just
15 a restatement of our recommendation, but what we're
16 recommending for the panel is that the panel
17 recommend to CMS that CMS should reassess whether the
18 application of the two-times rule is still
19 appropriate for complexity adjustment eligibility,
20 particularly at the higher end of the APCs.

21 We think that the panel should recommend
22 that CMS consider alternatives and propose them for

1 comment in future rulemaking, and with the rationale
2 that, like you have heard in the other presentations,
3 that Medicare payment should be consistent and
4 equitable and predictable, especially for complex
5 procedure combinations.

6 So, if we go to the last slide. And
7 this --

8 MS. AUGHENBAUGH: One minute remaining.

9 MS. BRANHAM: Thank you.

10 The last slide is simply a restatement of
11 the proposal that we have advanced to CMS multiple
12 times and in response to the RFI last year, that CMS
13 should consider a methodology of either the lower of
14 the current methodology, the two-times rule, or the
15 lowest GMC of the significant procedures in the next
16 highest APC.

17 And we believe that this proposal, if
18 finalized, would result in very minimal disruption to
19 the underlying APC system, but it would create some
20 flexibility and more appropriate thresholds for
21 certain procedures and certain APCs. And with that,
22 thank you very much.

1 DR. HAMBRICK: Thank you. Are there any
2 questions for the presenters from the panel? So, you
3 can ask it, and then if we have a log jam, then we'll
4 start raising hands. So, any questions from the
5 panel? Can we see the raised hands?

6 Oh, Douglas O'Brien.

7 MR. O'BRIEN: Thank you. Thank you,
8 Doctor.

9 This is more of an observation as a new
10 guy, but for those presenters -- you know, we've got
11 three very large healthcare corporations doing
12 presentations, and all three of them ostensibly were
13 arguing to improve the payment model for hospitals.

14 In future, I think it would be both
15 helpful to the panelists, but also in the interest of
16 transparency, when we have presentations like this,
17 it would be helpful to know a little more about why
18 this is an important issue to Philips or Boston
19 Scientific or J&J with a little more specificity.

20 I know you guys are supplying hospitals
21 and providing resources to hospitals, but I think it
22 would be right and prudent to include a little more

1 background as to why this is an issue for you as well
2 as hospitals. So, thank you very much.

3 DR. HAMBRICK: Ms. Artigue. We can't
4 hear you. Double unmute or something.

5 MS. ARTIGUE: Can you hear me now,
6 Dr. Hambrick?

7 DR. HAMBRICK: Yes, we can. Go ahead,
8 Ms. Artigue.

9 MS. ARTIGUE: I apologize. I get double
10 muted here. Thank you.

11 Just a quick observation. I think that
12 although the presentations were all related to the
13 complexity adjustment, I think the Philips
14 presentation is a little bit different because it
15 sounds like it's a consequence of the new codes being
16 actually structurally different than the predecessor
17 code, and then a double whammy with some of those new
18 codes being packaged.

19 So, quick question for CMS. Do we have
20 any more recent data on -- any preliminary data on
21 the new codes that we could use to assess the impact
22 of the complexity adjustment?

1 MS. BARRINGER: Sure. I can take this.

2 So, you know, we appreciate Philips
3 bringing this to our attention, and we encourage them
4 to please submit a public comment on this subject.
5 But for new HCPCS codes, it's been our longstanding
6 policy to use the best available information,
7 including crosswalking the new HCPCS codes to the
8 predecessor codes, and so we would continue to apply
9 that methodology here but encourage, as I said,
10 Philips to please submit a public comment on this
11 issue.

12 MS. ARTIGUE: And that's just part,
13 Ms. Marcos (sic), when there are multiple codes
14 representing the predecessor code?

15 MS. BARRINGER: You can crosswalk
16 predecessor codes and use multiple codes to do the
17 crosswalks.

18 MS. ARTIGUE: Okay. Thank you.

19 DR. HAMBRICK: Any other hands raised or
20 any other questions for any of the presenters? I
21 just see Ms. Artigue's. Any other ones?

22 Okay. I'm going to open it up for public

1 comments. Is anyone in queue to -- who would like to
2 make a comment? If so, please, Abby, check the chat
3 or just raise their hands.

4 Is anybody queued up to ask a question or
5 make a comment from the public?

6 MS. CESNIK: There's no questions in the
7 chat.

8 DR. HAMBRICK: Thanks, Ms. Cesnik.

9 Panel members, any further comments or
10 any recommendations with respect to any of the
11 presentations or all the presentations?

12 Okay. We will have another chance to
13 think about it over lunch. And if you have any, we
14 can always come back and do recommendations if you
15 come up with something.

16 Next, we're going to talk about APC
17 assignment for endobronchial valve procedure. Gina
18 Aughenbaugh is going to give us the CMS overview.
19 And if Pulmonx, Gabriel Brown and Mr. Stuart
20 Langbein, can queue up and make a presentation after
21 Ms. Aughenbaugh.

22 MS. AUGHENBAUGH: Hello, everyone. My

1 name is Gina Aughenbaugh. I'm from the Division of
2 Outpatient Care. I will be providing a brief
3 overview of the endobronchial valve procedure APC
4 assignment.

5 CPT code 31647 is used to describe the
6 procedure associated with the placement of the
7 endobronchial valves in the airway of adult patients
8 with severe emphysema. CPT code 31647 is assigned to
9 APC 5155 level 5 airway endoscopal for CY26.

10 For CY27, we propose to maintain the APC
11 assignment of APC 5155 for CPT code 31647 with a
12 proposed payment rate of approximately \$8,300.

13 As we will hear in the presentation from
14 Pulmonx, they are requesting that CMS reassign CPT
15 code 31647 to a new technology APC, specifically APC
16 1575 with a payment rate of \$12,500.50. This
17 concludes my overview.

18 DR. HAMBRICK: Thank you. For those
19 following in the two-times rule, CPT code 31647 and
20 APC 5155 is on page 74 and the new tech assignment
21 mentioned Pulmonx is APC 1575 pages 8 to 9. And
22 note, Dr. Manaker's statements from earlier. Thanks.

1 Go ahead, Mr. Brown and Mr. Langbein.

2 MR. BROWN: Thank you for the summary and
3 to the entire panel for giving us the opportunity to
4 speak today.

5 My name is Gabriel Brown. I am the
6 director of market access at Pulmonx. We are the
7 manufacturers of Zephyr valves.

8 Stuart, did you want to --

9 MR. LANGBEIN: I am Stuart Langbein. I'm
10 a partner with the law firm Hogan Lovells Cadwalader,
11 and I work with Pulmonx.

12 MR. BROWN: Can we go to the next slide,
13 please? So, a quick bit of background. The
14 endobronchial valves are implantable valves indicated
15 for bronchoscopic treatment of patients that have
16 hyperinflation associated with their severe
17 emphysema. These are one-way valves that are
18 intended to block air from entering the hyperinflated
19 lobe of the diseased lung while allowing the trapped
20 air to escape.

21 Currently, CPT code 31647 is used to
22 report the insertion of endobronchial valves and it

1 maps to APC 5155. This is a level 5 airway
2 endoscopy, which is the highest level APC for this
3 clinical group.

4 The geometric mean cost for CPT 31647
5 significantly exceeds the geometric mean cost of APC
6 5155. Since there are no clinically and resource
7 coherent APCs available in which we could possibly
8 move this, the best is to move CPT 31647 to a new
9 technology APC.

10 Next slide, please. So, let's first
11 review what is involved with this bronchoscopic
12 alternative to lung volume reduction surgery. A
13 patient is anesthetized and intubated, usually in an
14 operating room or a specialty-based procedure room.
15 A bronchoscope is introduced into the lungs and
16 navigates towards the most diseased and hyperinflated
17 lobe.

18 Next, a catheter is delivered to perform
19 a physiological assessment test to confirm whether or
20 not the patient's lobe selection has collateral
21 ventilation. Once we've confirmed that final
22 assessment, a delivery catheter is then introduced

1 through the bronchoscope and used both for valve
2 sizing and valve placement.

3 Typically, this takes about four to five
4 valves, and this collapses the targeted hyperinflated
5 area of the lung and allows for expansion of the
6 remaining healthier lung tissue, thereby improving
7 overall lung mechanics.

8 Finally, the patient has post-anesthesia
9 recovery and is monitored for complications. This
10 technology is supported by fixed randomized control
11 trials showing that by reducing hyperinflation,
12 Zephyr valve treatment improves lung function,
13 breathlessness, exercise capacity, and quality of
14 life in patients suffering from severe emphysema.

15 Next slide, please. So, with that
16 backdrop, let's review the costs associated with this
17 procedure.

18 Here are the CPT cost statistics released
19 with the 2027 proposed rule for APC 5155. You can
20 see the codes are arranged from highest to lowest
21 geometric mean costs, and I've highlighted the
22 endobronchial valve procedure, 31647.

1 So, this data shows that 31647 -- I know
2 it's a little small, has a high geometric mean cost
3 of 11,456 with a not insignificant number of claims,
4 about 84. We believe when all of the 2025 data is
5 evaluated with the upcoming final rule, it will be in
6 the neighborhood of 100 claims.

7 The geometric mean cost for 31647
8 represents an amount that is 38% above the payment
9 rate for the APC. This translates to a loss of over
10 \$3,000 per procedure for the hospital. This
11 significant financial barrier restricts access for
12 Medicare beneficiaries who have severe emphysema.

13 Next slide, please. So, it is important
14 to know, and when we look at the data for the last
15 four years, geometric mean costs for 31647 have
16 actually been relatively stable and always
17 significantly exceeding the geometric mean costs of
18 APC 5155.

19 In summary, with no clinically relevant
20 and resource-coherent alternative APC in which to
21 move it, as the panel recommended last year, we are
22 requesting that CPT 31647 be assigned to new

1 technology level 38, APC 1575, which has a range from
2 \$10,001 to \$15,000. CMS --

3 MS. AUGHENBAUGH: One-minute reminder.

4 MR. BROWN: Thank you.

5 CMS acknowledged the panel's
6 recommendation and left the proposal in place without
7 explanation other than it will re-evaluate in the
8 next cycle. As a result, the panel's recommendation
9 remains important. This would appropriately reflect
10 the actual costs shown in the CMS files for the last
11 several years and more appropriately cover costs
12 associated with providing endobronchial valves to
13 patients with severe emphysema.

14 Thank you for your time, and that
15 concludes my presentation.

16 DR. HAMBRICK: Thank you. Are there any
17 questions for the presenters? Seth?

18 DR. SETH: Yes. So, thank you so much
19 for that presentation.

20 So, you have had this since when? When
21 did this come out? When was this started being used?

22 MR. BROWN: The technology gained FDA

1 approval in 2018.

2 DR. SETH: Okay. So, 2018, it was -- it
3 came out. And then at this time, you're asking us to
4 move it to new technology because you want a better
5 reimbursement on what people are getting for what you
6 are using it for?

7 MR. BROWN: Because hospitals are
8 restricting -- are not doing this procedure because
9 of the significant financial burden of doing it with
10 this mapping to the current APC where they're losing
11 about \$3,000 per procedure. And so, that's the
12 reason.

13 DR. SETH: Okay. But is the frequency
14 being increased, or do you think it's being decreased
15 then because of this? Or can you comment on this at
16 all?

17 Can CMS have any indication? Has it been
18 going up or down?

19 MR. BROWN: It's been relatively stable
20 over the last four years that we looked at the data,
21 between 70 to 85, 90 procedures.

22 DR. SETH: Okay. Thank you.

1 DR. HAMBRICK: Any questions from any
2 other panel member?

3 Does the panel have a recommendation with
4 respect to -- oh, Ms. Artigue.

5 DR. SETH: You're muted. Still muted.

6 MS. ARTIGUE: Sorry. I don't know why
7 it's reverting. Can you hear me now? I apologize.

8 MR. BROWN: Yes.

9 MS. MOHR: Yes, we hear you.

10 MS. ARTIGUE: Yeah. I just have a
11 question for CMS to see if there's any feedback on --
12 I know I went back and looked last year. We did
13 indeed make the recommendation to move it to the new
14 tech APC, and there wasn't a whole lot of dialogue
15 about it from CMS, except that they were going to
16 reevaluate.

17 Any feedback as to why? Was it related
18 to the low volume? That it's still the same outcome
19 this year?

20 MR. RICE: This is David Rice. I can
21 speak to that a little bit. Of course, we can't go
22 too far beyond what we've said publicly, particularly

1 in a public comment period, but you're right that one
2 of the things that we've talked about before that we
3 consider in whether or not something with a -- a
4 service with a geometric mean cost that is either
5 above or below by a significant amount, the current
6 APC to which it's assigned is the volume of that
7 particular procedure, and whether or not there's
8 sufficient volume to, you know, have confidence in
9 whether or not the procedure is actually more or less
10 costly than the APC to which it's assigned.

11 And then, of course, we've also talked
12 about sort of the degree to which, if something is a
13 two-times violation, the degree to which it is a two-
14 times violation, whether it is far beyond what else
15 is in the APC or if it is, you know, over but close.

16 So, those are things we've talked about
17 in the past for broadly things we consider in
18 reassignments of APCs or of services to different
19 APCs.

20 MS. ARTIGUE: Thank you.

21 DR. HAMBRICK: Dr. Levin?

22 DR. LEVIN: Yeah. This is also a

1 question for the CMS side of things.

2 Is there any guidance as to when
3 something is no longer considered new technology?

4 MR. RICE: I can do -- take that one as
5 well. There is not a specific cutoff point for
6 something to be assigned to a new technology APC, you
7 know, as far as there's not anything that says it has
8 to have, you know, only been on the market for two
9 years or three years or anything like that, if that's
10 your question.

11 DR. LEVIN: Yeah, got it. Thank you.

12 DR. HAMBRICK: Mr. Fazio?

13 MR. FAZIO: Yes, I'm just curious. Is
14 CMS actively looking at adding a new APC for this
15 situation, for this, you know, particular category?

16 DR. HAMBRICK: So, let me take that one.

17 In general, I think as was mentioned, we
18 are in rulemaking so what the -- what the NOSA
19 proposed rulemaking reflects thinking on that date,
20 you know, July 7th, and the thinking of the --
21 thinking of the agency at this point.

22 Obviously, we're open to comment. The

1 comment period closes August 31st, but the staff is
2 sort of limited in what they're able to say, what
3 they're considering, what they're not considering
4 beyond what was placed in the rule. Does that answer
5 your question?

6 MR. FAZIO: Yes, thank you.

7 DR. HAMBRICK: Okay. Blake Dirksen,
8 Mr. Dirksen?

9 MR. DIRKSEN: Yeah, thank you, and thanks
10 to the presenters for the presentation.

11 DR. HAMBRICK: You're a little soft.

12 MR. DIRKSEN: Oh, I'm a little soft? All
13 right. How's that? A little better?

14 DR. HAMBRICK: A little soft. Yes,
15 indeed.

16 MR. DIRKSEN: All right. Thank you.

17 Yeah. Just, I know we commented or we
18 recommended last year to move to a new technology
19 APC, but considering the age of the technology, maybe
20 a recommendation to have CMS consider creating a new
21 APC, because there are several codes within this APC
22 that are a two-times violation.

1 DR. HAMBRICK: Would you like to put that
2 in a form -- a formal motion to that effect?

3 MR. DIRKSEN: Sure. I motion that CMS
4 consider creation of a level 6 APC for airway
5 endoscopy. I'm not sure how to end to that motion.

6 MR. FAZIO: Yes. Second.

7 DR. HAMBRICK: Second. Okay, thank you.

8 Discussion? All those in favor signify
9 by saying "aye."

10 DR. MANAKER: Hang on. Hang on,
11 Dr. Hambrick. So --

12 DR. HAMBRICK: Oh, somebody else? Oh,
13 Scott. Dr. Manaker.

14 DR. MANAKER: Yeah, thank you. Thank
15 you.

16 Yeah, so remember, I'm going to recuse
17 myself and abstain from any voting, but in looking at
18 the two times -- at the data in this APC, I would
19 point out that the -- there are no codes for a two-
20 times violation with significant volume, namely
21 greater than a thousand cases or 2% of the cases,
22 just as a point of information.

1 DR. HAMBRICK: Thank you.

2 Mr. Langbein, you have a response?

3 MR. LANGBEIN: Yeah, I wanted to make a
4 couple of quick points.

5 One, in response to what Dr. Manaker
6 said. You know, we're not suggesting there's a
7 technical two-times rule violation because the number
8 of claims that we see, 84, is not sufficient to
9 trigger the two-times rule violation as a technical
10 matter, but, you know, we are saying that there is,
11 you know, a consistent volume, as Gabriel said.

12 You know, volume numbers have been
13 relatively stable over the last four years, as well
14 as the geometric mean cost, and we think that should
15 give CMS some comfort with the continuous pattern
16 there that the geometric mean costs they're seeing --
17 that you all are seeing in the 27 proposed rule are,
18 you know, solid costs and do, you know, create the
19 means for a different APC assignment.

20 You know, we appreciate the notion of the
21 potential recommendation for assignment -- for
22 creation of a higher-paying APC in the family. We

1 would not expect from CMS's historical stance that
2 that would happen in the final rule when they haven't
3 proposed it, so that's why our -- the focus of our
4 request for the panel's recommendation -- you know,
5 whether it's an interim step as perhaps a new level
6 in the family is created in the future for assignment
7 to a new technology APC, because there's nothing --
8 no higher level that adequately would encompass the
9 geometric mean cost.

10 And, you know, we note that CMS has done
11 this with cardiac PET CTs where they, in 2020
12 initially, proposed to assign the codes 78431 to 33
13 -- to a clinical APC, but after comments about the
14 higher resources involved, CMS decided to put those
15 codes in a new technology APC.

16 So that's been, I just wanted to explain,
17 the focus of our recommendation for the panel to have
18 CMS assign this procedure to a new technology APC.
19 Thank you.

20 DR. HAMBRICK: Thank you. Mr. Fazio, did
21 you have a follow-up comment?

22 MR. FAZIO: I do not, no.

1 DR. HAMBRICK: Oh, your hand was still
2 raised.

3 MR. FAZIO: I'm sorry.

4 DR. HAMBRICK: That's all right.

5 I neglected to ask, did anyone from the
6 public want to make a comment? So I'm going to put a
7 little slight pause on -- and pull them into the
8 discussion portion of this.

9 Are there any comments or questions from
10 the public on this topic? I don't see any hands
11 raised.

12 Okay, let's carry on, panel, with the
13 discussion on the motion, which was to create a new
14 APC. Further discussion on that motion?

15 Okay, let's vote. All those in favor of
16 the recommendation, which was to create a new APC one
17 level higher, all those in favor say "aye."

18 (Simultaneous ayes)

19 Opposed?

20 DR. MANAKER: One abstention.

21 DR. HAMBRICK: Right. Abstentions are
22 last, Dr. Manaker.

1 DR. SETH: Scott's impatient.

2 DR. HAMBRICK: Yes, I see.

3 DR. SETH: I say nay. Nay.

4 DR. HAMBRICK: One.

5 MR. O'BRIEN: Nay.

6 DR. HAMBRICK: I have to do a little poll
7 here. So, I think I heard three nays. We have one
8 abstention. I thought I heard four or five ayes.

9 So let's let's do the ayes again
10 individually. All those in favor say aye.

11 (Simultaneous ayes)

12 Okay. Opposed, nay.

13 DR. SETH: Nay.

14 MR. O'BRIEN: Nay.

15 DR. HAMBRICK: Any abstentions?

16 DR. MANAKER: One.

17 DR. HAMBRICK: The ayes have it. Thank
18 you very much.

19 Okay. We'll move onto the APC assignment
20 and status indicator for peripheral nerve stimulation
21 therapy. Mr. Nate Vercauteren from the Division of
22 Outpatient Care will present an overview and Mr.

1 Marshall Bedder and Joe Milkovits from Neuralace
2 Medical will do the public presentation. Thank you.

3 MR. VERCAUTEREN: Good morning. Can
4 everyone hear me?

5 MS. ARTIGUE: Yes.

6 DR. HAMBRICK: You've got a little echo.

7 MR. VERCAUTEREN: Okay.

8 DR. HAMBRICK: Yes, we can hear you.

9 MR. VERCAUTEREN: Okay. I'm Nate
10 Vercauteren from -- I'm not sure why I'm getting an
11 echo.

12 DR. HAMBRICK: It's not horrible, so you
13 can go ahead.

14 MR. VERCAUTEREN: Okay.

15 DR. HAMBRICK: If it's horrible, we'll
16 start over.

17 MR. VERCAUTEREN: Okay, thank you.

18 I'm Nate Vercauteren from the Division of
19 Outpatient Care. I will cover the CMS overview and
20 background information on Neuralace Medical's
21 presentation on axon therapy.

22 CPT codes 0766T and 0767T became

1 effective January 1, 2023. The descriptor for CPT
2 code 0766T is transcutaneous magnetic stimulation by
3 focused low-frequency electromagnetic pulse,
4 peripheral nerve with identification and marking of
5 the treatment location, including non-invasive
6 electroneurographic localization, nerve conduction
7 localization when performed first nerve.

8 The descriptor for 0767T is
9 transcutaneous magnetic stimulation by focused low-
10 frequency electromagnetic pulse, peripheral nerve
11 with identification and marking of the treatment
12 location, including noninvasive electroneurographic
13 localization, nerve conduction localization when
14 performed each additional nerve, list separately in
15 addition to code for primary procedure.

16 HCPCS code 0766T became effective January
17 1, 2023, and was assigned to APC 5721, Level 1
18 Diagnostic Test and Related Services, with a static
19 indicator Q1, conditionally packaged.

20 For calendar year 2025, we finalized the
21 reassignment of HCPCS code 0766T to APC 5722, Level 2
22 Diagnostic Test and Related Services, with a proposed

1 payment rate of approximately \$311 and reassigned its
2 status indicator to S, separate APC payment.

3 For calendar year 2027, we propose to
4 continue assigning CPT code 0766T to APC 5722. For
5 calendar year 2027, the proposed OPPS payment rates
6 are based on available calendar year 2025 claims
7 data. We did not receive any claims data for HCPCS
8 0766T in 2023, 2024, or 2025.

9 We note that CPT code 067T with a status
10 indicator N is packaged. It is our long-standing
11 OPPS packaging policy that payment for add-on codes
12 is generally packaged into the primary procedure.

13 We've stated in prior final rules that
14 procedures described by add-on codes represent an
15 extension or continuation of a primary procedure,
16 which means they are ancillary, supportive,
17 dependent, or adjunctive to a primary service. Add-
18 on codes describe services that are always performed
19 in addition to a primary procedure and are never
20 reported as a standalone code.

21 Given the dependent nature and adjunctive
22 characteristics of procedures described by add-on

1 codes, payments for add-on codes is generally
2 packaged into the primary procedure.

3 For calendar year 2027, we propose to
4 continue assignment of status indicator N to CPT code
5 0767T.

6 Next, you will hear a presentation from
7 Neuralace Medical requesting the reassignment of CPT
8 codes 0766T and 0767T to a different, higher-paying
9 APC and requesting to change the proposed status
10 indicator for 0767T.

11 This concludes my presentation. Thank
12 you.

13 DR. HAMBRICK: Thank you. For those
14 following in the two-times rules, 0766T is in APC
15 5722, which is on pages 198 to 200 and APC 5724 on
16 pages 202 to 203.

17 Mr. Bedder, Mr. Milkovits --

18 MS. CESNIK: Dr. Bedder has his hand up.
19 Are you able to speak?

20 DR. BEDDER: Can you hear me now?

21 MS. CESNIK: Yes.

22 DR. BEDDER: Can you hear me now?

1 DR. HAMBRICK: Yes.

2 DR. BEDDER: Okay, great.

3 DR. HAMBRICK: Yes.

4 DR. BEDDER: Okay, sure.

5 So I want to say good morning and thank
6 you for the opportunity to present today.

7 So I'm Dr. Marshall Bedder, and I'm the
8 Chief Medical Officer at Neuralace, and today I want
9 to discuss our axon therapy device, which currently
10 is listed under CPT code 0766T and 0767T, as you have
11 heard.

12 You can advance the slide, please. The
13 goal of our presentation is to request that CMS
14 update the payment for the axon therapy device to
15 allow additional nerve treatment to be paid
16 separately. Our suggestion to CMS is to implement
17 the 2025 recommendation from the HOP Panel by
18 assigning the axon therapy device to APC 5724 and
19 changing the status indicator for 0767T to S.

20 Next slide, please. The axon therapy
21 device is a unique treatment device that provides a
22 non-surgical option for pain relief. It delivers

1 brief, focused, low-frequency magnetic pulses that
2 stimulate peripheral nerves to relieve chronic
3 neuropathic pain. This service is performed by a
4 physician or qualified healthcare professional who
5 controls the stimulation intensity and area of effect
6 based on detailed anatomical knowledge and with
7 patient interaction.

8 Next slide, please. Now, axon therapy
9 has been shown to be effective -- a very effective
10 option for painful diabetic neuropathy after
11 conservative medical management has failed and before
12 an invasive implantable procedure. Alternative
13 therapies and treatments such as spinal cord
14 stimulation can be very expensive and carry
15 additional risks.

16 The Veterans Administration has performed
17 over 10,000 axon therapy treatments over the past
18 four years with no adverse effects. The same
19 accessibility of axon therapy should be available to
20 Medicare beneficiaries.

21 Now, next slide, please. We also want to
22 stress that axon therapy and transcranial magnetic

1 stimulation, also known as TMS, have different
2 technical characteristics, making transcranial
3 magnetic stimulation, such as the NeuroStar TMS, an
4 inaccurate comparison with axon therapy. Primary
5 technical differences include magnetic field
6 settings, frequency, clinical indications, and target
7 area.

8 Axon therapy delivers a low magnetic
9 field, whereas the NeuroStar delivers at high
10 frequency. Axon, low frequency.

11 Finally, we want to note that axon
12 therapy requires fine tuning and calibration of the
13 stimulated nerve by the practitioner before the
14 therapy. We call this mapping, where we will isolate
15 the nerve to obtain paresthesia, as well as a motor
16 component to make sure that we are, in fact, in the
17 correct spot for maximum effect.

18 Now, the next slide. So, the second part
19 of our request is to change the status indicator for
20 0767T from N to S. Assignment to this status
21 indicator does not account for additional nerves
22 stimulated in the same session. Stimulation of an

1 additional nerve occurs in approximately half of all
2 patients.

3 Stimulation of the additional nerve
4 requires repositioning the patient, repositioning of
5 the coil. Again, mapping the nerves to obtain the
6 same effect as far as paresthesia in the region of
7 the pain, as well as the motor response. So, this
8 requires time and positioning and patient
9 coordination.

10 So, Neuralace has submitted a request to
11 the AMA to revise the code descriptors to help
12 further clarify the role of additional nerves in a
13 session.

14 Next slide, please.

15 MS. AUGHENBAUGH: One minute remaining.

16 DR. BEDDER: In closing, we reiterate our
17 request that CMS implement the HOP Panel 2025
18 recommendation to reassign axon therapy to APC 5724
19 and to change the status indicator for 0767T from N
20 to S.

21 We want to thank you for your time and
22 open the floor to any questions from the panel.

1 Hello?

2 MS. CESNIK: It looks like Jennifer
3 Artigue has her hand up, if you want to ask your
4 question.

5 MS. ARTIGUE: Yes. Can you hear me?

6 MS. CESNIK: Yes.

7 MS. ARTIGUE: Okay, great.

8 So, I have a question again for CMS. I
9 recall having this discussion last year and making
10 the proposal for exactly what the presenters are
11 asking for this year with the move of the code to an
12 APC 5724 and then also to change the status
13 indicator, but I don't recall final rule comment
14 addressing the recommendation of the panel.

15 Do any of the CMS staffers have some
16 feedback on the lack of implementation last year?

17 MR. O'BRIEN: Can anybody from CMS
18 acknowledge the question that was just asked?

19 DR. SETH: I was just going to ask CMS.
20 We can't hear anything from you guys, if you guys are
21 talking.

22 MS. GIERKE: Hi. Hi. This is Tonya

1 Gierke. I was just going to say that, you know, if
2 it was in the final rule last year, we would refer
3 you to that rule. You know, our discussions and
4 decisions are internal --

5 MS. ARTIGUE: Okay.

6 MS. GIERKE: -- but we do have the final
7 rule for individuals to refer to.

8 MS. ARTIGUE: Okay. Thanks, Tonya. I
9 didn't see anything there. I appreciate the
10 feedback.

11 MS. CESNIK: I think Nancy Dawson, I see
12 you have your hand raised.

13 DR. DAWSON: Yes, thank you. I have, I
14 think, an observation, but just to confirm what I'm
15 seeing.

16 On the two times data sheet for 0766T,
17 there are no -- the frequency is zero, correct? So
18 that means CMS, at this point, doesn't have any
19 comparison cost data for this. That's what I'm
20 reading, correct? Am I reading that correctly?

21 MS. ARTIGUE: Uh-huh.

22 DR. DAWSON: Yeah. Okay. Thank you.

1 MR. MILKOVITS: If I could add -- this is
2 Joe Milkovits from Neuralace Medical.

3 I just wanted to add that Neuralace
4 Medical had provided CMS with payment and invoices
5 that we have with the VA. And we had spoken with CMS
6 back in March with the idea that veterans have been
7 getting the axon therapy at a certain payment rate
8 that correlated to a certain APC, in our opinion.

9 And we were wondering why veterans were
10 getting access to the axon therapy, very happy with
11 it, and Medicare patients weren't. So, we were
12 asking CMS their thinking on the VA payment model as
13 being a proxy or a comp for a Medicare payment model
14 proposal, and I'm interested in CMS's thoughts on
15 that idea.

16 MS. GIERKE: Hi. This is Tonya Gierke.

17 MR. RICE: Oh --

18 MS. GIERKE: Oh, go ahead. Go ahead,
19 Dave.

20 MR. RICE: Yeah. I was going to say, you
21 know, again, public comment period, we can't speak
22 beyond what we said in the proposed rule. But, you

1 know, please submit a public comment on the rule, and
2 we would address any of those comments in the final
3 rule.

4 MR. MILKOVITS: Okay, thank you.

5 MS. CESNIK: And, Edith, if we're ready,
6 it looks like we do have a question from the public.

7 DR. HAMBRICK: Thanks.

8 MS. CESNIK: I heard someone speak, but
9 it's very quiet.

10 MS. MOHR: I am not showing any hands
11 raised.

12 MS. CESNIK: I'm seeing Patricia Levy
13 Zuckerman's hand raised.

14 MS. MOHR: I do see a hand raised from
15 Levy Zuckerman.

16 MS. LEVY ZUCKERMAN: Yeah. Can you hear
17 me?

18 MS. MOHR: Yes, we can.

19 MS. LEVY ZUCKERMAN: Yeah. I
20 accidentally hit the button. I may have a comment on
21 a later presentation. I just wanted to say it's been
22 a very interesting meeting, but I did not mean to

1 raise my hand on this one. So, I'm sorry for the
2 disruption.

3 MS. MOHR: Okay, thank you. No problem.

4 MR. MILKOVITS This is Joe Milkovits from
5 Neuralace Medical again.

6 Just wondering if it would be appropriate
7 to request that the panel take a motion to evaluate
8 the request that the company has made for APC
9 reassignment.

10 DR. HAMBRICK: Does anyone on the panel
11 have a recommendation?

12 Ms. Artigue, I see your hand raised. The
13 audio is too low. Can you hear me? Can you hear me
14 better? Is that better?

15 MS. BEAN: We can now.

16 DR. HAMBRICK: Okay. Ms. Artigue, you
17 have your hand raised?

18 MS. ARTIGUE: My question is I find it
19 interesting that 0766T has no reported volume at all.
20 I was curious to know what the volume of the other
21 code, 0767T, was. Just curious as to why not any
22 additional nerves are reported.

1 DR. BEDDER: It's Dr. Bedder.

2 I can say that no physician practice is
3 going to bill Medicare for a code that they know will
4 not be reimbursed in their office. But in the actual
5 -- you know, across the country, there are 50 sites
6 that are actually billing work comp, personal injury,
7 VA, community care, as well as VAs that are doing it
8 every day.

9 So, Medicare -- it's the classic chicken
10 and the egg.

11 MS. ARTIGUE: Right. Right. We've seen
12 this happen time and time again. Thank you. Thanks
13 for the clarification.

14 DR. HAMBRICK: Is there any
15 recommendation from the panel on this topic? We're
16 hearing none.

17 Thank you very much for your
18 presentation.

19 We'll move on to APC assignment for major
20 depressive disorder. Ms. Tonya Gierke will give us
21 the overview and Dr. Brandon Bentzley and Mr. Eric
22 Greig will make the public presentation.

1 Go ahead, Ms. Gierke.

2 (Technical interruption)

3 (Session is in recess)

4

5 (Session resumes)

6 MS. MOHR: Hello, everyone. I realize
7 you are waiting. We are still waiting for our
8 presenters to join, so it will be just a few moments
9 more. Thank you for your patience.

10 MS. CESNIK: Hi, Karen. And I think
11 we're going to start next with -- actually, we're
12 going to have to skip ahead because due to some
13 scheduling conflicts, and if we could go on to -- the
14 next presentation that we do, be the one from
15 Olympus, and then -- because Ruhya Patel, I see that
16 you're on.

17 If you're able to get started as soon as
18 possible, you could stay on and get your presentation
19 done, and then we could circle back to Magnus.

20 And I just wanted to let everyone know
21 that when you are -- if you need to leave the
22 meeting, please do not hit "end event," because this

1 is a recorded meeting, and then once that --

2 DR. HAMBRICK: Can you hear me?

3 MS. CESNIK: Yes, I can hear you, Edith.

4 DR. HAMBRICK: Okay. I switched to my
5 phone because I can't -- the room wasn't picking up,
6 so I wanted to -- so in a little bit, Karen, I'll go
7 out, when we go break for lunch, and then come back
8 in so we can do the room thing, but let's stay with
9 this right now.

10 MS. PATEL: May I start?

11 DR. HAMBRICK: I'm sorry?

12 MS. PATEL: Just let me know when you'd
13 like me to start speaking. It's Ruhy from Olympus
14 regarding the next presentation.

15 DR. HAMBRICK: Okay. We'll let you know.

16 MS. CESNIK: Karen, it looks like some of
17 the CMS -- are you still adding on the presenters?
18 It looks like some of the CMS staff is having
19 issues --

20 MS. MOHR: Yes. Yes.

21 MS. CESNIK: Okay. Sharing their
22 screens.

1 MS. MOHR: Right. Right.

2 DR. SETH: And are we going to have the
3 ability to have camera and mic, because mine just
4 came back on. Before, it was off.

5 MS. MOHR: Yes, you will be able to have
6 camera and mic as well.

7 MS. CESNIK: So, yeah, I just wanted to
8 let everyone know who's on, if you need to leave the
9 event, please hit "leave" and do not hit "end event."
10 I think that was our issue because once this event is
11 ended, we can't just restart it. So please do not
12 hit that button on the top of the screen.

13 DR. HAMBRICK: I think we have an
14 overview for -- Ms. Mohr, can we proceed?

15 MS. MOHR: Yes, you can. I am still
16 adding the rest of the presenters, but with your
17 current presenters, you're welcome to proceed.

18 DR. HAMBRICK: Okay.

19 MS. MARCOS: I can't share my screen.

20 MS. MOHR: All right.

21 MS. MARCOS: So I can share the slides.

22 MS. MOHR: Okay. This is Nicole?

1 MS. MARCOS: Yes, this is Nicole.

2 DR. HAMBRICK: I think the next -- just
3 so everyone knows, the next presentation we're going
4 to have is from Ruhy Patel at Olympus. We're going
5 to go slightly out of order.

6 MS. MOHR: Okay. And, Nicole, you can
7 share your screen now.

8 DR. HAMBRICK: Okay. Right, okay.

9 So, Ms. Gierke.

10 MS. GIERKE: Yes.

11 MS. PATEL: It's on to me now, I think.

12 MS. GIERKE: I've got a presentation,
13 just a little overview, before you get started.

14 So, hello, everyone. My name is Tonya
15 Gierke from the Division of Outpatient Care. I will
16 be providing the CMS overview and background
17 information for Olympus's presentation on endoscopic
18 submucosal dissection.

19 CMS established HCPCS Code C9779,
20 effective October 1, 2021, to describe the endoscopic
21 submucosal dissection performed during an endoscopy
22 or colonoscopy. C9779 is currently assigned to APC

1 5303, Level 3 upper GI procedures, and has a
2 geometric mean cost of approximately \$5,468.

3 The AMA CPT Editorial Panel created two
4 new Category 1 CPT codes, 4XX01 and 4XX02, effective
5 January 1, 2027, one code to describe the upper ESD
6 and one code to describe the lower ESD.

7 For calendar year 2027, we propose to
8 delete the C code and assign the upper ESD code to
9 APC 5303, Level 3 upper GI procedures, and the lower
10 ESD code to APC 5313, Level 3 lower GI procedures.

11 As we will hear in the presentation from
12 Olympus, they are requesting that we assign both ESD
13 procedures to APC 5331 to complex GI procedures.

14 This concludes my overview.

15 DR. HAMBRICK: Thank you. Now we'll hear
16 a letter submitted from Ruhy Patel.

17 Just so you know, CPT code 4XX01 is in
18 APC 5303, pages 113 and 114. CPT code 4XX02 is in
19 APC 5313, pages 117 and 118, and APC 5331 is on page
20 118.

21 You can go ahead, Ruhy Patel.

22 MS. PATEL: Thank you so much, and I

1 really do appreciate the flexibility of the panel, so
2 thank you again for that.

3 Can you hear me okay?

4 My name is Ruhy Patel, and I'm one of the
5 medical directors at Olympus. We would like the
6 Hospital Outpatient Committee to recommend to CMS to
7 consider reassignment of both new CPT ESD codes to
8 the APC 5331 for calendar year 2027.

9 C9779 did not distinguish between upper
10 and lower GI anatomy. It, therefore, cannot support
11 the CMS's proposed split.

12 Furthermore, the significance -- the
13 difference between the proposed upper and lower GI
14 payment is the lower GI being reimbursed at
15 \$3,233.31, which is 41% below the \$5,468.16 geometric
16 mean cost, which is \$5,751.52 median cost reported
17 for the combined ESD under C9779.

18 APC 5331 is the most coherent existing
19 group because it includes clinically challenging and
20 resource-intensive procedures. CPT 43497, or peroral
21 endoscopic myotomy, a POEM procedure, is an advanced
22 therapeutic endoscopic service clinically similar and

1 requiring highly specialized submucosal technique,
2 personnel, costly devices, which require in-depth
3 understanding of electrical, surgical principles,
4 anesthetic management, serious procedural risks, and
5 structured recovery.

6 ESD is associated with a wider
7 variability of procedure time, number of nights used,
8 and requires stabilization, especially in the lower
9 GI anatomy, and more complex closure techniques.

10 The costs of the electrical surgical
11 knives required to perform the ESD procedure are more
12 closely aligned with the devices required to perform
13 the procedures already aligned and assigned to the
14 APC 5331, which has the device offset percentage of
15 33.33%. In addition, frequently more than one knife
16 is required for this procedure.

17 Inadequate initial payment may discourage
18 hospitals from offering ESD, constrain beneficiary
19 access to minimally invasive organ-preserving
20 treatments, and create geographical disparities in
21 access to experienced centers. It may also encourage
22 substitution of more invasive procedures or delay in

1 adoption whilst hospitals wait for payment to catch
2 up with resource requirements.

3 I would add that ESD is the more
4 definitive procedure when it comes to these specific
5 types of lesions. Thank you.

6 DR. HAMBRICK: Thank you very much. Any
7 questions from the panel for the presenter? I don't
8 see any raised hands.

9 And are there any questions from the
10 public?

11 Is there any recommendation from the
12 panel with respect to this presentation? Okay, I
13 don't see any raised hands.

14 Okay. Well, thank you very much for your
15 presentation.

16 MS. PATEL: Thank you for your time.

17 DR. HAMBRICK: Thank you.

18 And now let's go back to the previous
19 presentation, which was APC assignment for major
20 depressive disorder.

21 Ms. Gierke up again. And we'll hear from
22 Dr. Bentzley and Eric Greig. Thank you.

1 MS. GIERKE: Hello. Hello again. I will
2 be providing the CMS overview and background
3 information for Magnus Medical's presentation.

4 Magnus Neuromodulation System is a
5 noninvasive, repetitive, transcranial magnetic
6 stimulation system that identifies an individualized
7 target located within the left dorsolateral
8 prefrontal cortex and delivers repetitive magnetic
9 pulses to treat treatment-resistant major depressive
10 disorder.

11 The AMA CPT Editorial Panel created four
12 new Category 3 CPT codes, 0889T, 0890T, 0891T, and
13 0892T, effective July 1, 2024, to describe this
14 therapy. These codes were assigned to new technology
15 APCs.

16 As we will hear in the presentation from
17 Magnus Medical, they are requesting that CMS maintain
18 the current APC assignments for the three CPT codes,
19 which describe the repetitive transcranial magnetic
20 stimulation treatment, specifically 0890T, 0891T, and
21 0892T, to better align with the costs of the therapy.

22 Magnus Medical asserts that the cost of

1 the hospital for providing this five-day treatment is
2 approximately \$5,500 per day. For calendar 2027, we
3 identified fewer than 100 claims for CPT codes 0890T
4 and 0892T.

5 As this is below the threshold of 100
6 claims for a service within a year, we propose to
7 apply our universal low-volume APC policy and use the
8 highest of the geometric mean cost, arithmetic mean
9 cost, or median cost based on up to four years of
10 claims data to assign these CPT codes to the
11 appropriate new technology APCs.

12 Because we identified more than 100
13 single frequency claims for CPT code 0891T, the
14 proposed new technology APC is based on the code's
15 geometric mean cost.

16 As a reminder, new technology APCs are
17 designated by cost bands, which allow us to provide
18 appropriate and consistent payment for designated new
19 procedures that are not yet reflected in our claims
20 data. We retain a service within a new technology
21 APC until we acquire sufficient data to assign it to
22 a clinically appropriate APC group.

1 This concludes my overview.

2 DR. HAMBRICK: Thank you, Ms. Gierke.

3 Just so people know, 0889T, APC 1511 is
4 on page 4. APC 890T, APC 1521 is on page 6 of the
5 two-times rule. 0891T, APC 1520, page 5. And 0892T,
6 APC 1523 is on page 6.

7 You may go ahead with your presentation.

8 DR. BENTZLEY: Thank you so much.
9 Appreciate having the opportunity to speak today.

10 Please advance to the next slide. My
11 name is Brandon Bentzley. I'm a psychiatrist. I was
12 previously at Stanford. I never thought I'd start a
13 company in my life, but we were doing research on
14 what is now a product called SAINT, or Stanford
15 Accelerated Intelligent Neuromodulation Therapy, and
16 saw extremely striking high rates of remission, as
17 well as rapidity to remission in days with this
18 treatment in severe treatment-resistant depression
19 using a combination of MRI targeting and targeted and
20 accelerated transcranial magnetic stimulation, which
21 I'll talk more about briefly.

22 We founded the company in 2020 to bring

1 this technology to the world, and were able to
2 receive FDA breakthrough designation, as well as
3 assignment to that new tech APC, which has allowed
4 this to enter into treating patients, which we're
5 very grateful and excited about.

6 So we'll talk a bit about that overview,
7 a bit about the evidence for SAINT in treating this,
8 and our request to retain the 2026 APC assignments
9 for SAINT.

10 Next slide, please. SAINT consists of a
11 few different steps. One is a structural and
12 functional MRI. That data is then sent to a cloud-
13 based computing system, which maps all the structural
14 and functional neural circuits to find the right
15 personalized location, as well as depth, amplitude,
16 and all the different orientation aspects of an
17 electromagnetic coil that's used to stimulate that
18 neural network in order to treat the depression.

19 I talk about that as background. We're
20 not actually talking about any coding or payment
21 today for those first steps. But today, the focus is
22 on delivery of the treatment.

1 So once that information for an
2 individual is computed, it's sent to the SAINT
3 neuromodulation system for a very intensive five-day
4 treatment, which is described by the 9091 and 92T
5 codes.

6 During these days, the patient's with us
7 for over 10 hours a day. The treatment itself is 10-
8 minute stimulation sessions on the hour every hour
9 for 10 hours, and the patient in between. These
10 patients are highly complex, usually have
11 suicidality, a lot of complex psychosocial issues,
12 comorbidities, and we deal with them throughout the
13 day to make sure that they stay safe.

14 When they're getting the treatments,
15 there is a frameless stereotaxic system, which is
16 very similar to what might be used even in a
17 neurosurgical suite that's used to place and then
18 maintain placement and orientation of the coil
19 throughout the treatment session, as well as proper
20 amplitude during these treatment sessions through the
21 five-day course.

22 Next slide, please. The whole reason I

1 left academia to start this company was because of
2 our striking results we found. We have many more
3 clinical trials that have since been published that
4 are randomized control trials, as well as large
5 naturalistic trials, long-term follow-ups. The data
6 is the same.

7 We find a very large separation between
8 sham and active treatment for remission. Remission,
9 on average, takes about three days. It's a five-day
10 total treatment. And compared to putting somebody on
11 a third or additional medication or conventional
12 forms of non-targeted treatment, our results are far
13 superior in remission rates.

14 Next slide, please.

15 MR. GREIG: Hi, this is Eric Greig from
16 Cooley. I'll be picking up from Brandon to talk
17 about the cost assignment and what we've seen.

18 As Tonya from CMS summarized, the costs
19 and expenses of the hospital are summarized in the
20 box at the left. That's primarily based on the costs
21 recognized by CMS through the new technology add-on
22 payment system in the inpatient setting, but those

1 hospital costs are the same.

2 We appreciated the HOP Panel's feedback
3 last year when this cost reporting issue by hospitals
4 was raised and identified. As we discussed then, in
5 initial 2024 data, hospitals were assigning the cost
6 for this procedure to inappropriate revenue codes or
7 with chargemasters that didn't reflect those
8 resources.

9 Those hospitals provided written feedback
10 to CMS confirming that, and the HOP Panel recommended
11 that CMS maintain their prior year new tech APC
12 assignments based on that feedback.

13 Those cost reporting challenges were
14 identified late in 2025, and while the health systems
15 worked to improve those processes through the year,
16 those changes didn't happen until 2026 when they are
17 now in the system. So, all of the 2025 data that
18 informs this 2027 rule was based on those inaccurate
19 cost reporting challenges.

20 Next slide, please. And here you see the
21 effect of those cost reporting issues throughout
22 2025, proposed reductions of up to 50 percent per

1 treatment day, which would severely restrict access
2 for this therapy.

3 Next slide, please. And the cost for
4 that is primarily focused with two health systems
5 that you see highlighted in red here, both of which
6 have written in to CMS to confirm that these costs
7 here do not reflect the resources required for SAINT,
8 and they are the result of cost reporting issues that
9 have since been corrected but are not yet reflected
10 in the 2025 claims data.

11 So, Magnus is requesting that CMS and the
12 HOP Panel once again retain the existing new
13 technology APC assignments for these three procedure
14 codes for these delivery days so that patients with
15 severe depression may continue to access this
16 therapy, as you see summarized on the next slide in
17 the conclusion.

18 DR. HAMBRICK: Thank you. Did you want
19 to discuss your conclusory slide or do you want to
20 let it speak for itself?

21 MR. GREIG: Sure. I thought I was a
22 little bit over, but I appreciate the opportunity.

1 DR. HAMBRICK: Oh. If she said you were
2 over, you were over.

3 MR. GREIG: All right, thank you. I
4 think it speaks for itself.

5 DR. HAMBRICK: Okay, great. All right.
6 Any questions for the presenters? Yeah,
7 I think you were over.

8 DR. SETH: Yes. Can I ask a quick
9 question?

10 DR. HAMBRICK: Yes, go ahead.

11 DR. SETH: Sorry. So, you guys think
12 this is underused or underreported? Because I
13 understand you're saying this is very effective for
14 depression and everything else, like, I understand
15 that.

16 But are you saying that hospitals are not
17 using it enough or it's just not being used?

18 MR. GREIG: The costs are being
19 underreported, or they were in 2025 at least. The
20 utilization adoption, I think, is continuing at pace
21 with the current new technology APC assignments.

22 DR. SETH: Okay. And so, you're saying

1 for us to just keep it at what you're doing?

2 MR. GREIG: Exactly.

3 DR. SETH: CMS, do we have any comments
4 on the data?

5 DR. HAMBRICK: Yes. I would say that the
6 data speaks for itself in the two-times rule. And
7 hospitals -- not specifically speaking to this
8 particular proposal. Hospitals come up with what
9 they charge for services and it's not unheard of that
10 the charges might be a variance from what the
11 presenters feel, you know, are appropriate.

12 However, if you look at the rules and the
13 two times data, that's the current reporting that we
14 have on the services.

15 I think Ms. Artigue was next, followed by
16 Dr. Manaker.

17 We can't hear you, Ms. Artigue. Am I the
18 only one who can't hear Ms. Artigue?

19 MS. GIERKE: No, she's still muted.

20 DR. SETH: Nope, we can't hear you
21 either.

22 MS. MOHR: I am trying to get her unmuted

1 at this moment.

2 DR. HAMBRICK: Oh, okay.

3 MS. MOHR: If you are on your phone,
4 could you please check to make sure it's --

5 MS. ARTIGUE: Okay. Can you hear me now?
6 I think we were successful.

7 MS. MOHR: Yes, we hear you.

8 MS. ARTIGUE: Awesome. So, my question
9 is for CMS, and it's in relation to the cost report
10 discrepancy.

11 I understand that it was two providers
12 that had a larger amount of claims here, and that
13 they reported to CMS that there were some incorrect
14 cost reporting. In that reporting to CMS, did they
15 indicate when the issue was expected to be resolved?
16 Was it, in fact, the most of last year was still
17 incorrect?

18 MR. RICE: I see Eric has his hand up. I
19 think he might want to speak to that.

20 MR. GREIG: Ms. Artigue, if CMS doesn't
21 have that information available, I can say that in
22 the letters that were provided, the resolution did

1 occur in May of this year for one of the providers,
2 and is occurring presently with the other provider.

3 MS. ARTIGUE: Okay. So, they're at risk
4 for another year of incorrect cost report -- well,
5 partial year, at least, of incorrect cost report --

6 MR. GREIG: Partial year.

7 MS. ARTIGUE: Thank you. I appreciate
8 that clarification. Thank you.

9 DR. MANAKER: My turn, Edith?

10 DR. HAMBRICK: Oh, sorry. I was on mute,
11 trying to make sure I didn't have any background
12 noise.

13 DR. MANAKER: That's okay.

14 DR. HAMBRICK: Yes, Dr. Manaker.

15 DR. MANAKER: Thank you.

16 Just a quick question. If I heard you
17 correctly, the treatment was provided on an inpatient
18 basis, and now it's being provided on an outpatient
19 basis, and the costs that we're talking about now
20 being reported are for outpatients, not inpatients,
21 correct?

22 MR. GREIG: That's correct.

1 DR. MANAKER: And the data were -- the
2 data problems and the cost reports were identified in
3 late '25, and it took the hospitals six plus months
4 to correct their cost reports?

5 MR. GREIG: I'm afraid that is also
6 correct. And I think if you speak to some of the
7 physicians around that process, they were happy to
8 have it occur then, because it was a Herculean effort
9 to have some of these updates for a new technology
10 that was not previously recognized, but that is
11 correct.

12 DR. MANAKER: And so, I'll just make an
13 observation that if we do nothing, as Ms. Artigue
14 mentioned, we'll have partial cost reports correct
15 for a minority of months this year, and really
16 wouldn't have correct data for a full year until
17 2027, when we're thinking about the 2028 schedule.

18 DR. HAMBRICK: Anymore --

19 DR. SETH: Can I ask a quick question?
20 How long has this been out there for?

21 MR. GREIG: This launched commercially
22 initially in the second half of 2024.

1 DR. SETH: So, still relatively young?

2 MR. GREIG: Correct.

3 DR. HAMBRICK: Are there any more
4 questions or any questions from the public?

5 Does the panel wish to make a
6 recommendation with respect to this presentation?

7 MS. ARTIGUE: I'd like to make a
8 recommendation.

9 DR. HAMBRICK: Go ahead, please.

10 MS. ARTIGUE: I recommend that CPT code
11 0890T, 0891T, and 0892T remain in the new technology
12 level 25, APC 1525, in light of the continued cost
13 reporting implications.

14 DR. HAMBRICK: Is there a second?

15 DR. SETH: I will second it.

16 DR. HAMBRICK: Discussion?

17 All those in favor, signify by saying
18 aye.

19 (Simultaneous ayes)

20 Opposed, nay.

21 DR. LEVIN: Nay.

22 DR. HAMBRICK: Abstention?

1 The ayes have it.

2 So, Ms. Cesnik, you want to break now for
3 45 minutes to an hour?

4 MS. CESNIK: Maybe 45 minutes.

5 DR. HAMBRICK: Okay.

6 MS. CESNIK: And that way we get somewhat
7 back on track time-wise.

8 DR. HAMBRICK: Okay. So, we're going to
9 make break for 45 minutes. So, everybody be back at
10 five minutes after one.

11 DR. SETH: Thank you.

12 DR. MANAKER: Thanks. See you then.

13 DR. HAMBRICK: Thank you.

14 (Session is in recess at 12:20 p.m.)

15

16 (Session resumes at 1:05 p.m.)

17 DR. HAMBRICK: Good afternoon, everyone.
18 This is Edith Hambrick with the Sixth Advisory Panel
19 on Hospital Outpatient Payment Meeting. We're going
20 to have a discussion on payment for cellular and/or
21 tissue-based products. Cory Duke from the Division
22 of Outpatient Care will --

1 MR. DUKE: All right. Thanks,
2 Dr. Hambrick.

3 So, hello, everyone. My name is Cory
4 Duke, and I'll be providing an overview regarding the
5 payment for cellular and/or tissue-based products
6 presentation.

7 So, in the calendar year 2026 OPPS and
8 ASC final rule with comment period, CMS finalized the
9 proposal to unpackage skin substitute products from
10 the application services and establish several APCs
11 based on relevant product characteristics when these
12 products are used during a covered application
13 procedure paid under the OPPS.

14 These services may be described by CPT
15 codes 15271 through 15278. Currently, on the screen
16 are CPT codes 15271 through 15278 are being
17 displayed.

18 Secondly, CMS finalized the proposal to
19 align skin substitute categorization for payment
20 purposes consistent with their FDA regulatory status
21 for 361 human cells, tissues, and cellular and
22 tissue-based products, also known as HCTPs, and the

1 device types, pre-market approvals or PMAs, and
2 510Ks.

3 Additionally, in that 2026 rule, CMS
4 sought comments on whether products that are not in
5 sheet form are appropriately considered skin
6 substitutes for the purposes of providing separate
7 payments. Examples of these products could include
8 gels, powders, ointments, foams, liquids, or injected
9 products that are listed in the nontraditional units
10 such as cubic centimeters, milliliters, or
11 milligrams.

12 We requested feedback on whether these
13 products could be appropriately described as part of
14 the CPT administration codes in the range 15271
15 through 15278. CMS ultimately finalized in the OPPS
16 that these products would continue to be paid through
17 their packaged payment mechanism.

18 On the next slide, we will see that
19 effective April 1, 2026, CMS created new HCPCS level
20 2 codes to describe the application of non-sheet form
21 skin substitute products, including HCPCS codes
22 G0681, G0682, G0683, and finally G0684.

1 Consistent with the current payment
2 arrangements under the OPPS for products that are not
3 in sheet form, these HCPCS application codes were
4 assigned to a status indicator of N to indicate that
5 payment for the application of non-sheet form skin
6 substitute products is packaged.

7 Again, these HCPCS codes were effective
8 April 1 of 2026 and are shown on the slide being
9 presented.

10 In a moment, you will hear from the
11 Alliance of Wound Care Stakeholders regarding
12 specific requests on the payment for the
13 administration of non-sheet form skin substitute
14 products paid under the OPPS.

15 This concludes my review, and I will now
16 hand it over to our public presenters. Thank you.

17 MS. SCHAUM: Good afternoon. My name is
18 Kathleen Schaum, and I'm the president of Kathleen D.
19 Schaum & Associates, Inc., and I am a member of the
20 Alliance of Wound Care Stakeholders. I have spent
21 near five decades educating.

22 Next slide, please. I have spent nearly

1 five decades educating wound care practitioners,
2 outpatient departments, et cetera. And certainly,
3 you know, things get very confusing around these CTPs
4 (sic).

5 I do want to mention that CMS has now
6 determined that these non-sheet CTPs (sic) are
7 covered and reimbursable and, in fact, have stated
8 that they should be paid at the same payment rate for
9 outpatient departments and ASCs as the physicians,
10 which is 12714.

11 Then, as Cory has just mentioned to you,
12 because the 15271 and 15278 did not pertain to the
13 non-sheet products, CMS created four new application
14 codes, the G0681 to G0684.

15 So, at this moment, I don't know whether
16 this is an oversight or just what, but these codes
17 have not been assigned to an APC group, which will be
18 very, very difficult for the outpatient departments
19 to implement this payment for these non-sheet
20 products because you have to have a payer. You have
21 to have an application code as well as the product
22 code.

1 So therefore, we are recommending that
2 the panel recommend to CMS that they assign the non-
3 sheet CTP (sic) application codes to the same APC
4 groups as the sheet application codes. This would
5 keep it very consistent, and it would be easy to
6 teach to the outpatient departments because they are
7 very confused about what to do for the non-sheet
8 products.

9 So we are asking that you recommend that
10 we map the application code G0681 to APC group 5053
11 and the application code of G0683 to the APC group
12 5054, and that will then be consistent through all
13 the sites of service, which I believe is CMS's goal.

14 And I thank you very much.

15 MS. NUSGART: Thank you, Kathy. My name
16 is Marcia Nusgart, and I am the founder and CEO of
17 the Alliance of Wound Care Stakeholders, and we
18 represent physician specialty societies, clinical and
19 patient associations, wound care provider groups,
20 wound care clinics, and business entities operating
21 in the wound care area.

22 So what I'd like to do is talk to you

1 today about total contact casts, TCCs. We brought
2 this issue up in 2024, and the panel voted to support
3 it, and we're asking for the same this afternoon.

4 So the issue is that the CPT guidance
5 shows debridement codes and TCC application on the
6 same date of service, and these codes should map to
7 APC's 5052-5053/5102. The CPT assistant guidance
8 states that code 29445, application of rigid total
9 contact lay cast, is the appropriate code to report
10 for the total contact cast application.

11 So TCC is used to reduce the pressure and
12 or shear forces on a lower extremity wound, typically
13 on the plantar surface. The cast improves the
14 ability of the wound to heal. So if a wound
15 debridement is performed, any primary or secondary
16 dressing materials used to cover the wound would be
17 included in the debridement and would not be
18 separately reported.

19 However, a TCC is not considered a wound
20 dressing and is not included in the debridement
21 procedure, therefore the cast application should be
22 coded in addition to the code for the appropriate

1 level of debridement it performed and should be
2 mapped to APC 5102.

3 What's not on the slide is by accident we
4 need to change the status indicator of 29445 from T
5 to S since that wasn't included on the last bullet on
6 this slide and in the recommendation. Because the
7 application of a TCC is labor intensive and the cost
8 of the product is not insignificant, the S status
9 indicator will provide 100% of the allowable rate for
10 29445 when performed at the same encounter when a
11 debridement is performed. If the status indicator
12 remains as T, the facility will only receive 50% of
13 the allowable rate.

14 So, therefore, our recommendation is that
15 the panel requests that -- the alliance requests that
16 the panel recommend to CMS to pay HOPD as separate
17 APCs for the TCC APC 5102 and to change the status
18 indicator from T to S when a debridement is performed
19 on the same date of service consistent with the AMA
20 CTP coding guidance.

21 Thank you so much, and I'll be happy to
22 answer any questions.

1 DR. HAMBRICK: Are there any questions
2 from the panel or the presenters?

3 MS. NUSGART: And we also have two one-
4 minute speakers too.

5 DR. HAMBRICK: Okay. So first let's
6 start with the panel.

7 MS. NUSGART: Thank you.

8 DR. HAMBRICK: I think, how about you,
9 Dr. Manaker? GiGi, I don't think that's one of our
10 panelists. So why don't you go ahead, Dr. Manaker.

11 DR. MANAKER: Thanks, Edith. I have a
12 question for the presenters about the non-sheet
13 products.

14 So the payment of \$127 is for a single
15 sheet, correct? But there's no information here
16 about the volume of the gel, the powder, the
17 ointment, et cetera. So without a volume here,
18 somebody could put a bucket of gel or ointment on and
19 be billing multiple times, correct?

20 MS. SCHAUM: Dr. Manaker, I understand
21 exactly what you are saying. And, in fact, that was
22 the dilemma that CMS had.

1 And if you read in the physician fee
2 schedule proposed rule, that you will see that they
3 are recommending in that proposed rule that you
4 determine the number of units for the non-sheet
5 products simply based on the size of the ulcer that
6 you are putting it on.

7 So, for example, if it is a two square
8 centimeter ulcer, you are only going to get paid for
9 two centimeters of the J-code -- or not the J-code,
10 but of the Q or the A-code, which most of these are
11 A-codes. So that seems to be taken care of when you
12 read the rule for the physician fee schedule.

13 And so that's why we really actually need
14 CMS to duplicate that instruction over here in the
15 outpatient department, as well as to be sure they
16 apply the AP -- the G0681 and the G0683 to an APC
17 group. Otherwise, you can't bill them out and you
18 can't align them.

19 So that is exactly why we need to be sure
20 that APC group is assigned. So they're not paying
21 for the non-sheets based on the volume that you
22 bought. They're only paying for the number of square

1 centimeters of the wound surface that it gets applied
2 to. That's, at least, what they have told us in the
3 physician fee schedule.

4 DR. MANAKER: Right. So that's the
5 physician?

6 MS. SCHAUM: Does that make sense?

7 DR. MANAKER: Yeah, it makes sense for
8 the physicians, but that's why I don't understand it
9 here for the hospital. If you lay it on thick versus
10 you lay it on thin, you're using twice as much gel or
11 powder or ointment. So how is that going with twice
12 the expense? And I don't see how you can accommodate
13 for that here.

14 MS. SCHAUM: No. They just -- they just
15 need that direction, all right? Because the
16 direction is missing in this fee schedule, but it's
17 over in the physician fee schedule, and the ability
18 to bill out for the application, which everything is
19 predicated on the size of the ulcer that you're
20 getting the application for.

21 We need to have the application codes
22 assigned to an APC group. So if they make those

1 things mirrors of each other, then indeed you would
2 not be able to bill for any more product than the
3 number of square centimeters that it was applied to.

4 DR. MANAKER: So, in essence, you're
5 recommending they change the G-codes to the size of
6 the wound?

7 MS. SCHAUM: No. The G-codes already are
8 described to the size of the wound.

9 DR. MANAKER: I see.

10 MS. SCHAUM: So the G-codes are correctly
11 described, they're just not assigned to an APC group
12 for OPPS. All right?

13 And if that happens, if that would happen
14 and we would have direction in regards to the -- how
15 you report the product code based on the square
16 centimeters of the ulcer that it's received,
17 everything aligns.

18 Right now, the instruction for that is
19 missing, as well as the assignment of G0681 and G0683
20 to an APC group. That's all we need to have happen.
21 If that happens, then they should be perfectly
22 aligned with the physician fee schedule.

1 MS. ARTIGUE: Ms. Schaum, the issue with
2 the CPT codes not being in an APC is because they're
3 status indicator N packaged, correct?

4 MS. SCHAUM: Yes. But now -- and that's
5 -- and Medicare has said that now they are covering
6 them and reimbursable, so that N status indicator, of
7 course, has to be changed.

8 MS. ARTIGUE: Right.

9 MS. SCHAUM: So if they take the N away
10 and they apply these two codes to an APC group, just
11 like the ones for the sheet products, then indeed the
12 solution is made.

13 DR. TETTELBAACH: So this is Bill
14 Tettelbach. I have a little bit of a problem with
15 switching this to the sheets because a gel and a
16 powder do not go by square centimeters. It's going
17 to go by volume -- it's going to go by total square
18 surface area or volume of the product used.

19 So there will be not an alignment for the
20 provider who needs to buy it and bill it. So that
21 needs to be figured out.

22 And I think that's part of the

1 methodology that still is going to be on the MAC
2 level, far as I can tell.

3 MS. SCHAUM: Well, I don't know about
4 that, Dr. Tettelbach, because in the proposed rule
5 for the physician fee schedule it clearly says,
6 clearly, that because there is these different size
7 and weights, et cetera, of the non-sheet products, we
8 are not using that at all. Instead, we are saying,
9 based upon the size of the ulcer, then that is the
10 number of units we are going to pay for.

11 So let's say the ulcer is 2 square
12 centimeters. It doesn't matter how much non-sheet
13 product you bought, you're going to be able to bill
14 out for the product code two times 127.14. That's
15 it. It doesn't matter if you had 100 units of the
16 non-sheet product. You could only bill out for two
17 because that's the size of the ulcer that it covered.

18 DR. TETTELBAACH: Yeah. So I think that
19 is part of what is in question on the total surface
20 area versus just flat surface area. So that is, I
21 think -- you know, under the current practice, gels
22 are reported using Q codes assigned to each product.

1 The units, you know, vary, you know, according --
2 that's why we've never billed them out that way,
3 because it doesn't necessarily fit.

4 So I think the methodology is still being
5 figured out. I think that will still be on a MAC
6 level for that.

7 MS. SCHAUM: I don't think so.

8 DR. TETTELBAACH: Okay.

9 DR. HAMBRICK: So let me jump in here in
10 the sense that with the physician fee schedule, yes,
11 it's a proposal that has been put out by CMS, but I
12 think we all recognize that there are two different
13 systems and two different forms of payment and two
14 different methodologies.

15 So while I've allowed some discussion
16 about what's going on in physician's fee schedule,
17 the issue is an OPPS issue. So if we can confine our
18 remarks to -- from the presenters and any other
19 speakers to the -- how OPPS has proposed to pay for
20 that.

21 DR. TETTELBAACH: Okay. And then I have
22 one other question for Marcia on the total contact

1 cast, which I totally support, but are we in support
2 of, you know, the fact that the 50% rule still would
3 cut the cost of the procedure by half? Or in most
4 cases, hopefully the contact cast would be paid full,
5 and the other, if it was a debridement, would be the
6 50%. I just want to clarify that.

7 DR. HAMBRICK: You're asking the
8 presenter?

9 DR. TETTELBACH: That was with Marcia.

10 MS. NUSGART: Oh. Kathy, can you answer
11 that if that? Is that -- I wasn't sure.

12 MS. SCHAUM: Yes.

13 MS. NUSGART: Thank you so much.

14 MS. SCHAUM: I think, if I understand
15 you, is that what Marcia was saying, that the one
16 thing that was missing off the bottom of the slide
17 was not only did we want to be sure that the total
18 contact cast was able to be separately paid and paid
19 in its own APC group, but that we would need to
20 change the status indicator from a T to an S.

21 Because otherwise, both of them would be
22 -- you know, one would be paid at 100, one would be

1 paid at 50%. But if you change the status indicator
2 -- the TCC to an S, then it would allow that to be
3 paid at 100% because it's so very labor and product
4 cost heavy.

5 So, the TCC would be paid at -- if it's
6 changed to an S, would be paid at 100%.

7 DR. TETTELBACH: And I'm in support of
8 that. Thanks for clarifying that. That's great.
9 Thank you.

10 DR. HAMBRICK: Dr. Manaker, did you have
11 a follow-up?

12 DR. MANAKER: Yeah. I'm still struggling
13 with the volume issue. And so, you have two wounds,
14 they're the same square centimeters, but in three
15 dimensions, one is a burn or a donor skin graft site
16 and it's thin and relatively superficial, and another
17 wound, same square centimeters, but it's a deep gouge
18 with a valley, and you're going to fill in that
19 valley with any of these products, but a lot more
20 than that superficial skin donor site.

21 So, I'm still struggling here with the
22 volume issue.

1 DR. HAMBRICK: Are there any more panel
2 members with questions for the presenters?

3 I understand we have public --

4 MS. ARTIGUE: This is Jennifer. I'm
5 sorry. I put into the chat the descriptions of those
6 G codes, if that's at all helpful.

7 DR. HAMBRICK: Okay. So, presenters -- I
8 mean, public, I understand -- I see someone whose
9 hand is raised that I have as Gigi. I don't know who
10 that is, but if you are from the public and you want
11 to make a comment, please identify yourself and your
12 organization.

13 DR. GORDILLO: Sure. My name is Gayle
14 Gordillo. I was one of the one-minute speakers for
15 the Alliance.

16 I'm a board-certified plastic surgeon and
17 senior medical director of wound services at UPMC
18 Health System based in Pittsburgh, Pennsylvania. In
19 my role, I have oversight of 23 hospital-based wound
20 centers.

21 And my request to the panel is to
22 basically follow the recommendations of the Alliance

1 and assign new application codes for non-sheet
2 cellular and/or tissue-based products as recommended
3 by the Alliance for Wound Care Stakeholders. So, put
4 them in the same APC groups as the sheet products.

5 I'm also requesting the panel to request
6 from CMS to provide guidance for the correct code and
7 unit assignment of these new application codes and
8 the non-sheet products. I will need to properly
9 inform and create necessary processes for the 23
10 centers under my supervision, as well as inform and
11 educate our billing specialist partners.

12 And I do want to address the issue of
13 volume versus area. And I will tell you that for the
14 sheet products, the issue has been addressed as area
15 and not volume because of the very issue that
16 Dr. Tettelbach brought up -- or the other panel
17 member.

18 Even -- any wound, even if it's a sheet,
19 we don't get credit for the sides of the wound,
20 right? If it's a centimeter deep, all you get is a
21 two-by-one. So, that is the precedent that has
22 already been set.

1 DR. HAMBRICK: Thank you.

2 Is there an MJ?

3 MS. JOHNSON: Yes, this is -- can you
4 hear me?

5 DR. HAMBRICK: Yes.

6 MS. JOHNSON: Are you able to hear me?
7 Yes, I can hear you.

8 DR. HAMBRICK: Yes.

9 MS. JOHNSON: Yes. My name is Melissa
10 Johnson. I'm the Regional Director of Wound Care and
11 Hyperbaric Services for Piedmont Health Care outside
12 of Atlanta, and I just want to get some information
13 on supporting the CCI edit change with the status
14 indicator.

15 Just the current challenges that we're
16 seeing in the hospital outpatient department where
17 we're taking on the full cost of both procedures,
18 including provider time, casting supplies, and wound
19 care resources. This loss of reimbursement for TCC
20 may discourage utilization despite its proven
21 clinical benefit.

22 The patient care impact remains. This is

1 the gold standard for offloading diabetic foot ulcers
2 and is associated with improved healing outcomes.
3 Combining debridement with immediate offloading is
4 considered best practice and helps reduce healing
5 time, complications, infections, and amputations.

6 The financial disincentives may result in
7 less frequent use of TCC, potentially leading to
8 longer treatment courses and increased downstream
9 healthcare costs. Although the debridement, TCC, and
10 the CCI edit limits reimbursement when both services
11 are performed on the same leg, maintaining evidence-
12 based use of total contact casting in the HOPD is
13 critical to achieving superior wound healing
14 outcomes, preventing amputations, and supporting our
15 long-term quality and value-based care objectives.

16 So, we would like to continue and support
17 the recommendation of the Alliance to have the status
18 indicator for the CCI edit with TCC changed. Thank
19 you.

20 DR. HAMBRICK: Thank you for your
21 comment.

22 Anything related to CCI, if you're

1 referring to the National Correct Coding Initiative,
2 would not be within the purview of the panel, so the
3 panel knows.

4 Any more questions from the panel? Or
5 any more public, I guess, first? Any more public?
6 Raised hands or -- okay.

7 So, any more discussion from the panel,
8 questions, so forth and so on? If not, is there a
9 recommendation from the panel with respect to this
10 presentation?

11 All right. Thank you for your
12 presentation.

13 And we'll move on to the next one, which
14 is APC Assignment for Gastric Electrophysiology
15 Mapping Procedure. Ms. Nicole Marcos will present
16 the OPPS overview, followed by Greg O'Grady from
17 Alimetry. Thanks.

18 MS. MARCOS: Thanks, Dr. Hambrick.

19 Hi, everybody. My name is Nicole Marcos,
20 and I will be providing the CMS overview and
21 background information for Alimetry's presentation on
22 GEMS.

1 GEMS is short for Gastric
2 Electrophysiology Mapping with Simultaneous Patient
3 System Profiling. It's a non-invasive service, and
4 it analyzes the motility of the stomach using gastric
5 data collected through an adhesive patch combined
6 with real-time patient report symptoms to identify
7 specific areas of gastric dysfunction.

8 Effective July 1, 2023, and based on a
9 new tech application that we received for the GEMS
10 service, we created HCPCS code C9787 and assigned it
11 to APC 5723, which is level 3 diagnostic tests and
12 related services.

13 Effective July 1, 2024, HCPCS code C9787
14 was deleted, and it was replaced by CPT code 0868T.
15 We assigned CPT code 0868T to APC 5723, which is the
16 same APC to which its predecessor code HCPCS code
17 C9787.

18 For CY2027, we propose to continue to
19 assign CPT code 0868T to APC 5723. Proposed payment
20 rate of approximately \$435.

21 As you will hear in a moment, Alimetry is
22 requesting that we assign 0868T to a higher-paying

1 clinical APC providing level 4 diagnostic tests and
2 related services as an option. Proposed APC payment
3 for the level 4 diagnostic tests and related services
4 APC is approximately \$1,065.

5 For CY2027, there are 28 single frequency
6 claims available for CPT code 0868T for rate setting,
7 and the GMC is approximately \$2,460.

8 This concludes my presentation. Thank
9 you.

10 DR. HAMBRICK: Thank you. Greg O'Grady.

11 DR. O'GRADY: Thank you for having me.
12 Have you got my slide deck there available?

13 So thank you for having us this
14 afternoon. I'm Greg O'Grady. I'm the CEO of
15 Alimetry. I'm a GI surgeon and one of the developers
16 of this technology.

17 So as discussed, we're advocating that
18 this code should be increased to a higher level of
19 payment. We have with us today our macro consultants
20 in case there's any technical questions.

21 So the next slide, just some background
22 about the test, what it is. It is a new procedure in

1 medicine. It's a new category of diagnostics. And
2 this is a high-resolution mapping procedure
3 comparable, if you're aware of cardiac field, or
4 comparable to cardiac mapping procedures using high
5 density of arrays to generate sophisticated data on
6 electrophysiology.

7 It was first cleared in 2023 by the FDA,
8 now five clearances. And it has rapidly accumulated
9 evidence with over 55 clinical studies.

10 It's largely used by specialists in the
11 field. It's a specialist definitive procedure. And
12 what it does is it's the only test capable of
13 differentiating gastric neuromuscular disorders, so
14 true nerve and muscle diseases of the stomach from
15 central and sensory causes of chronic nausea, often
16 used in patients with suspected gastroparesis.

17 The evidence shows it typically changes
18 management, usually towards less invasive care
19 directions in the hands of specialists.

20 We'll go to the next slide, please. So
21 to show you some of the procedure itself, it requires
22 a 64 high-resolution electrode array. And this is a

1 very difficult piece of equipment to manufacture.
2 It's costly and it costs \$990 for that single use
3 high resolution patch. And currently, the
4 assignment, as you'll see, does not even cover half
5 of the patch required to perform this test, meaning
6 that many patients simply -- it's not available.

7 It requires over five hours of clinic
8 time, so a significant requirement for the service.
9 And surveys have shown that that leads to a
10 significant amount of nursing or tech time engagement
11 with the patient in the clinic room, \$15,000 worth of
12 equipment and other consumables.

13 So although it's an intensive test,
14 though, the savings come downstream from performing
15 the test from getting patients off these invasive
16 treatment pathways. Studies have shown about 50%
17 reductions in annual healthcare utilization, about
18 \$5,000 per patient, and about 84% of cases change
19 management decisions. And it has over 2.7 times
20 higher diagnostic yield than other tests currently
21 available, which are really nonspecific, such as
22 gastric emptying, which is performed with nuclear

1 medicine scintigraphy.

2 So it's resource intensive, but
3 clinically impactful and reduces downstream costs.

4 We'll go to the next slide. So one of
5 the factors as to why CMS has placed it in the 5723
6 category has been due to these comparators that are
7 available, which are actually low-resolution
8 techniques, and we do not consider them clinically
9 equivalent.

10 We have made this case a number of times
11 to CMS over recent years, but it was good to see it
12 strongly supported in a recent statement from an
13 international working group of over 47 clinicians
14 from a wide variety of institutions, which
15 specifically made this statement in a international
16 guideline, that the test is not comparable to
17 comparable services from a technical, clinical
18 utility, resource requirement, or reimbursement
19 viewpoint that have been used as comparators to date.

20 Go on to the next slide. So we're asking
21 that this test be placed in a higher diagnostic
22 category. It's currently in APC 5723, and this is on

1 three things. CMS's own cost data, which shows a
2 mismatch, the resource profile mismatch, and this
3 international expert consensus showing that the
4 comparators are a mismatch.

5 Next slide. Just to show you the --
6 CMS's own cost data. The current geometric mean cost
7 is \$2,460 versus the proposed category of 435, which
8 as mentioned does not cover half of the array cost.
9 That's more than 6.5 times the comparator costs with
10 28 claims in the recent year.

11 There's a number of headwinds to getting
12 that claims up. Specifically, the cost of the
13 procedure is misaligned versus what is paid, so
14 hospitals are simply not performing it.

15 MS. AUGHENBAUGH: One minute reminder.

16 DR. O'GRADY: Next slide, please.

17 Thank you.

18 There's a number of data tables here
19 which are available offline. Just to draw attention
20 that the current comparator tests are not comparable
21 in terms of the number of electrodes or the resource
22 use, and there's been zero billed cases for one of

1 the key comparators showing that it's not really in
2 active clinical use.

3 Next slide. There's a strong precedent
4 for moving cases up to a higher diagnostic category,
5 including this wireless capsule test last year, which
6 has a consumable fee of \$250 less than the GEMS
7 procedure, but was still moved up to a higher
8 category.

9 We'll go to the next slide. So to
10 summarize, we're advocating and hopeful of your
11 recommendation that this test is moved up based on
12 the inappropriate comparisons with cost data, the
13 expert consensus showing its comparator is
14 inappropriate, and also the resource profile
15 mismatch.

16 And we thank you for your time and
17 consideration today.

18 DR. HAMBRICK: Thank you very much.

19 Any questions from the panel?

20 Questions from the public while the panel
21 mulls over the presentation?

22 DR. O'GRADY: Maybe I can just mention

1 that as well, another one of the tests available
2 that's commonly used by these specialists, the
3 SmartPill test is in the category 5301, an upper GI
4 procedure, which is, again, much more resource
5 coherent with a consumable that costs between \$500
6 and \$1,000.

7 And really, the high cost of the
8 consumable in particular as well as the resource
9 allocation is making this test not available to many
10 patients in the Medicare service.

11 DR. HAMBRICK: Thank you.

12 Any questions from the panel?

13 DR. SETH: Yes, I have a quick question
14 for CMS. Do we have, like, a number of times this
15 has been used?

16 MS. MARCOS: Yeah. We have -- I believe
17 it's close to 30 single frequency claims in looking
18 at the recently available claims data.

19 DR. O'GRADY: Most of the patients
20 suffering these tests are young women, about 10% to
21 15% of Medicare.

22 DR. HAMBRICK: Excuse me. Excuse me,

1 Mr. O'Grady. We have a panel question.

2 Ms. Artigue?

3 MS. ARTIGUE: Thank you. Hi. Can you
4 hear me?

5 DR. HAMBRICK: Yes, we can.

6 DR. SETH: Now we can't.

7 MS. MOHR: I'm sorry. We cannot hear
8 you. Try unmuting your device again.

9 MS. ARTIGUE: Okay, I'll try this again.

10 MS. MOHR: There you go.

11 MS. ARTIGUE: So, for the HCPCS code
12 0868T in APC 5723, is it not a violation of the two-
13 times rule because it's so infrequent? The table
14 shows only 28.

15 DR. HAMBRICK: To whom are you addressing
16 that question, Ms. Artigue?

17 MS. ARTIGUE: CMS. I'm sorry,
18 Dr. Hambrick. To the CMS staff. I'm just wondering
19 why it's not a two times violation.

20 DR. MANAKER: It's not more than 1,000
21 cases or 2% of the volume.

22 MS. ARTIGUE: That's what I thought.

1 Thank you.

2 DR. MANAKER: And the reminder is on the
3 bottom of all the pages. It shows the asterisk marks
4 the significant ones where the frequency is greater
5 than 1,000 or it's greater than 99 and 2%.

6 MS. ARTIGUE: Thank you.

7 DR. MANAKER: So, you can see the codes
8 that are asterisked.

9 MS. ARTIGUE: Thank you.

10 DR. HAMBRICK: Any questions with respect
11 to this procedure?

12 Are there any recommendations with
13 respect to this procedure?

14 DR. MANAKER: I'll make a motion that we
15 recommend moving it to 5724.

16 I've been looking through all the
17 different codes in the two APCs, and there's a lot of
18 polysomnography and EEG studies that would be, I
19 think, more equivalent, more homogeneous from a
20 research -- I'm sorry, resource allocation in 5724.

21 DR. DAWSON: And I second that motion.

22 MR. DIRKSEN: Second the motion.

1 DR. SETH: I will second that motion.

2 DR. HAMBRICK: Discussion?

3 All those in favor of the motion signify
4 by saying aye.

5 (Simultaneous ayes)

6 Opposed, nay.

7 Any abstentions?

8 Motion carries. Thank you very much.

9 And last but not least, we have a
10 presentation on radiation treatment software.

11 Ms. Nicole Marcos will give us the overview, and
12 Dr. Daniel Kim will make the public presentation.

13 MS. MARCOS: Hi again. This is Nicole
14 Marcos, and I will be covering the CMS overview
15 background for Novocure's presentation on MAXPOINT.

16 MAXPOINT is a software used with tumor
17 treating field therapy for glioblastoma. It analyzes
18 a patient's MRI data and electrical property mapping
19 to generate an individualized transducer array layout
20 optimized for that patient-specific tumor location
21 anatomy. It also handles placement verification,
22 helping ensure the arrays deliver therapeutic field

1 strength to the target site.

2 The CPT editorial panel created CPT code
3 1025T, effective January 1, 2026, to describe the
4 service. It's a brand-new code. The code with the
5 descriptor is listed on the slide.

6 In the CY2027 OPPS ASC proposed rule, we
7 propose to assign CPT code 1025T to APC 5611, which
8 is level 1 therapeutic radiation treatment
9 preparation, and it groups together various radiation
10 treatment preparation services under the OPPS.

11 As we will hear in the presentation from
12 Novocure, they are requesting that we reassign CPT
13 code 1025T to APC 5613, which is level 3 of the
14 current clinical APC to which it is assigned.

15 Since the code was made effective January
16 1, 2026, we currently do not have any available
17 claims data for the service.

18 This concludes my overview.

19 DR. HAMBRICK: Thank you.

20 For those looking in the two-times rule,
21 1025T, APC 5611 is on pages 187 and 188 and 5613 is
22 on page 188.

1 Go ahead, Dr. Kim.

2 DR. KIM: Thank you. My name is
3 Dr. Daniel Kim, and thank you for the opportunity to
4 present today.

5 I'm a radiation oncologist at the Inova
6 Schar Cancer Institute, and I'm speaking on behalf of
7 Novocure to discuss their MAXPOINT planning software
8 for tumor treatment.

9 Next slide, please. The goal of this
10 presentation is to request that CMS update MAXPOINT's
11 payment from APC 5613 level 3 therapeutic radiation
12 treatment preparation. Currently, MAXPOINT is listed
13 under APC 5611 level 1 therapeutic radiation
14 treatment preparation.

15 Next slide, please. So MAXPOINT is
16 advanced treatment planning software for tumor
17 treatment, what we call TT fields for glioblastoma.
18 It's been standard of care for over a decade, and
19 this new software will allow us to now use patient-
20 specific scans and imaging data to determine the
21 precise array placement for Novocure's Optune Gio
22 device.

1 This will allow us to optimally deliver
2 electromagnetic fields to the tumor area. This code
3 took effect on January 1st of this year.

4 Next slide, please. The existing APC
5 5611 consists of CPT codes that represent basic or
6 rapid calculations to aid in treatment planning. No
7 advanced computer modeling is required. MAXPOINT
8 does not fit into this category because it is a
9 finite element analysis software that uses imported
10 scans to run an analysis and produce a solution for
11 electrode array placement for the physician.

12 The analysis process involves
13 computational processing and cannot easily be done
14 without software code.

15 Sorry, was there a question? All right.

16 MS. MOHR: Will everyone please remain
17 muted while the presenter is presenting.

18 DR. KIM: Thank you so much.

19 Novocure believes that APC 5613 is a more
20 accurate category for CPT 1025T. The other CPT codes
21 in this category are advanced planning software codes
22 that require detailed user input and can produce

1 complex visual results to aid the physician.

2 MAXPOINT is very similar in complexity,
3 both technically and clinically, to 3D planning codes
4 and other CPT codes in this category. Technically,
5 the tumors must be contoured to identify abnormal
6 areas during planning, and the abnormal tissue must
7 be segmented to create an electrical conductivity map
8 of the brain and tumor.

9 Clinically, the physician must interpret
10 images during the planning process to identify areas
11 of tumor progression and study, analyze, and select
12 the best array option provided by the software.

13 Next slide, please. In closing, Novocure
14 is reiterating its request that CMS implement the HOP
15 Panel's 2025 recommendation to reassign MAXPOINT to
16 APC 5613.

17 Thank you for your time, and open for any
18 questions from the panel.

19 DR. HAMBRICK: Are there any questions
20 from the panel?

21 DR. SETH: I think Scott and I have
22 questions.

1 DR. HAMBRICK: Oh, I see. Okay. Why
2 don't you start.

3 DR. SETH: Sorry, Scott.

4 All right, quick question. Is this
5 specific to Optune usage for GBMs?

6 DR. KIM: Yes, Optune Gio for GBMs.
7 That's correct.

8 DR. SETH: Okay. So you're asking --
9 okay.

10 So this code is specific for an Optune
11 device? How is Optune being used right now? Like,
12 there's a code for just Optune already. You guys are
13 not new technology. You've been around for a while,
14 so that's what I'm trying to figure out. Why is this
15 becoming more of an issue than before?

16 DR. KIM: Yeah. So Optune tumor treating
17 field for glioblastoma has been around for a while,
18 as you've mentioned.

19 This is specifically regarding MAXPOINT,
20 which is advanced treatment planning software for the
21 tumor treating fields, which hasn't existed before.

22 DR. SETH: So then you can --

1 DR. KIM: Has not existed before.

2 DR. SETH: Okay. So then you're saying
3 that this software program will tell you how to
4 actually place Optune on the patients differently
5 from what it has done?

6 DR. KIM: Yes, that's correct.

7 DR. SETH: So this is going to be
8 different from what this is now?

9 DR. KIM: Yes, exactly.

10 DR. SETH: All right. There's no other
11 competing Optune or anything else out there, right?
12 There's only one Optune out there? There's no other
13 company that does what Optune does?

14 DR. KIM: So, yes, I am not aware of any
15 other tumor treating field companies, certainly not
16 any ones that are FDA approved or in clinical use in
17 the US currently. I'd also like to -- I see someone
18 had raised their hand.

19 We also have a couple of physicians who
20 have used MAXPOINT, and Dr. Whitley, and then also --

21 DR. SETH: Okay. So we can get to them
22 in a minute.

1 DR. KIM: -- who can also maybe speak to
2 that as well, yeah.

3 DR. SETH: Right. So does this improve
4 the usage of Optune? Like, do the patients have
5 better overall survival, decreased risk reoccurrence,
6 progression-free survival is increased? Why would we
7 use this instead of just using Optune?

8 DR. KIM: Yeah. So the efficacy is not
9 something that has been studied to date, but it is, I
10 think, a fair question if that's within the scope. I
11 would say we don't have that data now, but as this
12 comes out and we are using it, that is of interest in
13 the field.

14 DR. SETH: Okay, thank you guys.

15 Scott?

16 DR. MANAKER: Yep, thanks.

17 So my question is a little different
18 about how the hospital purchases this. So this is
19 software. The MR images and other data are entered
20 into the software. Does the hospital buy the
21 software once and uses it on the next gazillion
22 glioblastoma patients who comes through, or is it

1 somehow a one-and-done and the hospital's got to buy
2 this and we're going to see the cost for it for every
3 individual patient?

4 DR. KIM: So I believe it's like a
5 treatment planning software for radiation. I'm not
6 sure if you're familiar with things like RayStation
7 or like ARIA, Eclipse --

8 DR. MANAKER: No.

9 DR. KIM: -- but essentially it could
10 either be purchased either as a one-time or a
11 licensing fee, and then that software could be used
12 multiple times for patients.

13 And if you guys don't mind,
14 Dr. Wilkinson, who is a medical director at Novocure,
15 probably has a better answer for that as that is
16 probably more company specific. Can I call on him?
17 He's on the call right now as well.

18 DR. WILKINSON: Hi. This is --

19 DR. HAMBRICK: Wait, wait, let me see if
20 Dr. Levin's question is related or different. If
21 it's different, then we'll let you speak.

22 DR. KIM: Okay.

1 DR. LEVIN: Mine is slightly different.

2 DR. HAMBRICK: Okay. So why don't you go
3 ahead and answer that in follow-up?

4 DR. WILKINSON: My name is Craig
5 Wilkinson. I'm the VP of U.S. Medical Affairs at
6 Novocure.

7 While this falls under the business and
8 commercial side, MAXPOINT will be done on a yearly
9 contract with sites, and it will be used for any
10 patient during that time. So it does not matter per
11 patient. That answers the question. It's very
12 simple and very basic. And it's is cloud-based
13 software, so it is simple for sites to use.

14 DR. MANAKER: So that means if the
15 hospital buys it and they've got a site license,
16 we're going to see a charge for that one annual
17 purchase once, if there's one glioblastoma patient,
18 but we'll see that same charge come through 100 times
19 if there's 100 patients?

20 DR. WILKINSON: No. So there's a
21 licensing agreement between Novocure and the site for
22 MAXPOINT software, and then this code charge would be

1 for the actual planning that's done for any specific
2 patient.

3 DR. MANAKER: Okay.

4 DR. HAMBRICK: Dr. Levin.

5 DR. MANAKER: Thank you.

6 DR. WILKINSON: Sure.

7 DR. LEVIN: Yeah. So in hearing your
8 presentation, I think that I understand how this is
9 similar to 77295, conceptually. I guess I'm just
10 trying to understand why -- how this is different
11 from 77290 in terms of the workflow and what is
12 involved.

13 I get the one is 2D and one is 3D, but
14 can you help explain how that is functionally
15 different?

16 DR. KIM: Yes, let me try that. The --
17 so I think the main difference is the fact that with
18 MAXPOINT, the -- with the treatment planning
19 software, a lot of it is -- you know, I would say the
20 parallel would be what we're doing right now for
21 other modalities that we're treating, particularly,
22 you know, I mentioned 3D or even IMRT, which is what

1 we're doing in the radiation oncology clinic, and
2 that also we're using treatment planning software for
3 tumors.

4 In both cases, we're using patient-
5 specific scans and imaging data, whether it's CT or
6 MRIs, and we're developing, like, precise patient-
7 specific plans.

8 I think the difference there is exactly
9 that. Now that we're able to better image the tumor
10 and better segment the tumor and then also, you know,
11 in the MAXPOINT software, we're segmenting areas of
12 radionecrosis, we're able to better deliver the
13 electromagnetic field.

14 And I think going back to that efficacy
15 question, you know, there was a paper by Balow that
16 looked at the therapeutic doses of tumor treating
17 fields for looking at deeper, you know, brainstem
18 tumors. And I think that did show significantly
19 higher, you know, say, electrical dose using the
20 MAXPOINT software.

21 And then since the efficacy question was
22 raised, I would point out that, you know, when IMRT

1 was initially approved, it was not approved based on
2 any efficacy data, whether survival or anything.
3 It's basically just dosimetric rationale, better
4 target conformality, et cetera. The randomized data
5 really came later.

6 And then if I may, I'd like to also call
7 -- ask my colleague, Dr. Whitley, who's also using
8 MAXPOINT software in his clinic, and he is on the
9 call as well. May he also speak to your question as
10 well, sir?

11 DR. LEVIN: Sure.

12 DR. HAMBRICK: Is there a response to
13 that particular question?

14 DR. LEVIN: That's fine. Thank you.

15 DR. WHITLEY: All right. Hi, I'm Alex
16 Whitley. I'm a radiation oncologist practicing in a
17 community practice at Central Alabama Radiation
18 Oncology. Thank you for having me on.

19 The MAXPOINT software, getting a couple
20 of the questions, is materially different than the
21 previous treatment planning system that was utilized.
22 Some -- you may be aware, but it was based on kind of

1 three coordinates of the central tumor location in
2 the skull. So, that was the previous treatment
3 planning system, so it wasn't tailored specifically.

4 And this treatment planning system really
5 takes the physician input of what is tumor necrosis,
6 what is resection cavity, what is enhancing tumor,
7 and the physician is going in and delineating all
8 those targets now, which is materially different than
9 what it was before. So, lots of physician input akin
10 to contouring organs at risk and the tumor target
11 for, say, a 3D or IMRT plan.

12 So, it's very similar to that now from a
13 physician input. And a treatment plan is generated
14 specifically based on the tumor location and those
15 biophysical properties within the brain.

16 We do know, and Dr. Kim mentioned the
17 Balow paper, that with increasing power density
18 within an area, we do see improved outcomes, granted
19 retrospective analysis. But clearly, we know, at
20 least in cell culture, as well as that retrospective
21 analysis, that increasing power density in an area
22 portends better outcomes and better results.

1 So, that's what this treatment planning
2 system does from a standpoint of patient care. And
3 having treated patients with this treatment planning
4 system, it has done that for them.

5 DR. LEVIN: Thank you.

6 DR. HAMBRICK: Blake Dirksen?

7 MR. DIRKSEN: Yeah, this is Blake
8 Dirksen.

9 DR. HAMBRICK: -- is next.

10 MR. DIRKSEN: Thank you for the
11 presentation.

12 Out of curiosity, the optimization
13 algorithm that develops this, are you merely
14 optimizing where the, essentially, panels are placed
15 on the head or is there, like, an energy depth? What
16 are all the parameters that are kind of built into
17 that optimization?

18 You know, when we look at some of the
19 level 3 planning codes, like the complex MRT code and
20 the 3D codes, there's thousands of factors being
21 computationally optimized, you know. Just kind of
22 give me a scale for how complex the plan that can be

1 delivered to the patient.

2 And then, do they only get -- follow-up
3 question. Are they only getting the one plan for
4 their course of treatment or is this something that
5 needs to be adjusted, kind of adapted during the
6 course? Thank you.

7 DR. WHITLEY: I guess I'm happy to answer
8 that question. It's adapted as their MRIs change
9 over the course of their illness. We all know that
10 the high rate of recurrence of this type of tumor and
11 the lethality of it, so it is adapted, at least in my
12 clinic, on a Q2 month basis. So, if the imaging
13 declares a change, then we may adjust the location of
14 the electrical arrays to account for that.

15 Getting at your initial question, it --
16 and others can address this too, but the biophysical
17 properties of those structures.

18 So, I mentioned, you know, some of the
19 things that we contoured during the target
20 delineation planning process is because all of those
21 structures have different biophysical properties for
22 energy deposition with the arrays. So, all of those

1 properties matter.

2 For instance, you're contouring whether
3 there's a calvarial defect related to their, you
4 know, craniotomy and resection. So, all of that is
5 going as an input into it and you're fusing CTs and
6 MRIs to account for all of that data input.

7 And then the physician input is, like I
8 said, very similar to, say, a 3D or MRT contouring
9 session. And then the computer calculations bring
10 back multiple different plans where you're selecting
11 based on calvarial defects or energy deposition and
12 tumor coverage or enhancing tumor coverage for
13 appropriate delivery.

14 DR. WILKINSON: And if I may add, if you
15 have questions about specific technical calculations
16 and what is done internally in the software, we can
17 provide a written response to you by 8/31, if needed.

18 MR. DIRKSEN: Just a real quick follow-up
19 on that. If the plan and contouring does intend on
20 being adapted, is the -- is this new technology code
21 that we're discussing for per course or would this
22 then be re-reported for each time that the

1 calculation is re-completed -- re-done?

2 DR. WHITLEY: As a practitioner, I would
3 think it would be just like we would adapt during a
4 radiation treatment delivery over a course of
5 therapy, say, for a head and neck cancer. Over the
6 course of their illness, you know, let's say six
7 months in, a patient shows some progression in the
8 posterior temporal lobe, I may adjust that plan at
9 that point.

10 And the randomized trial was continued
11 through first progression, stopping at second
12 progression. So, potentially, you're adapting once
13 over the course before you would transition to a
14 different course of treatment.

15 MR. DIRKSEN: Thank you.

16 DR. HAMBRICK: Dr. Seth?

17 DR. KIM: Oh, I apologize.

18 DR. SETH: No. He asked my question and
19 that's what I wanted him to answer because I wanted
20 to know how often they would be using this.

21 And yeah, so, Optune is usually put on
22 these patients and then you keep going with it as

1 long as, you know, you get scans every two months to
2 make sure they're doing okay. So, I'm assuming this
3 is not going to be charged every time you see the
4 patient, but just every time you re-evaluate with an
5 MRI. And the only thing I don't want is a vendor-
6 specific code for them because it should be agnostic
7 of vendors, I believe.

8 DR. KIM: Yeah, I think that's a very
9 fair point. But I think -- I would like to just
10 clarify. It wouldn't just -- just because you get
11 the MRI, but I would -- not just because you get the
12 MRI, we would - you would be charging this, but if
13 you take the MRI and you're going to do a re-plan on
14 it.

15 As Dr. Whitley's saying, kind of the
16 equivalent is, you know, get an MRI and you're
17 adapting to new patient anatomy. Because we know the
18 tumor treatment and field planning with MAXPOINT
19 where we're finding the electrical field distribution
20 strongly influenced by tumor size, location,
21 geometry, tissue conductivity, electrode array
22 positioning on the scalp, and post-surgical changes.

1 So, you can imagine that with these
2 patients with glioblastomas, as we know, after they
3 have surgery and radiation, the cavity -- there's
4 cavity dynamics that shrink. There's tissue necrosis
5 that can happen. And so, just because we're getting
6 an MRI, we wouldn't try to charge it. But if we used
7 the MRI, put it into MAXPOINT and created a new
8 MAXPOINT plan, adjusted the arrays, then we would
9 expect to -- the equivalent would be, again, like a
10 re-plan for radiation.

11 DR. HAMBRICK: Thank you. Any more
12 questions for the presenters? Does anyone have --
13 does anyone from the audience wish to ask a question?

14 MS. MOHR: Alex Whitley, you can unmute
15 and ask your question if you like.

16 DR. HAMBRICK: Thank you.

17 DR. WHITLEY: I just spoke. So, I think
18 Dr. Kim covered and what I highlighted is that the
19 physician inputs basically the same as what we would
20 do for 3D or MRT, delineating all these structures
21 and kind of alluded to the adaptation over the course
22 of a patient's disease course.

1 DR. HAMBRICK: Thank you.

2 Any more questions from the panel about
3 the presentation?

4 Is there a recommendation from the panel
5 with respect to the presentation? Thank you very
6 much.

7 MR. DIRKSEN: Yeah, this is --

8 DR. HAMBRICK: Oh, sorry. Go ahead.

9 MR. DIRKSEN: I was trying to duck in
10 there under the timeline there.

11 Yeah, I think I want to create a motion.
12 I motion that we move -- I'll make sure I get the
13 number right here -- HCPCS code 1025T. I motion that
14 we recommend CMS consider moving that from level 1
15 therapeutic radiation treatment up to -- I'm going to
16 recommend level 2 therapeutic radiation treatment
17 preparation. It seems like a pretty big jump up to
18 three if it's to be reported multiple times.

19 So, I make the recommendation that we
20 move the CPT code up to APC 5612 level 2 therapeutic
21 radiation treatment prep.

22 DR. HAMBRICK: Second?

1 DR. LEVIN: Second.

2 DR. SETH: So, you want to move it to
3 level 2? I'm good with that. I'll third.

4 DR. HAMBRICK: Okay. Discussion --

5 MR. DIRKSEN: And then we'll have claims
6 data here in a couple years.

7 MS. ARTIGUE: Yeah, that's fair. Doesn't
8 the recommendation need to come --

9 DR. HAMBRICK: I thought that was from
10 the panel -- that was not from a panel member?

11 MR. O'BRIEN: Yes.

12 MR. DIRKSEN: That came from Blake
13 Dirksen, panel member.

14 DR. HAMBRICK: All right.

15 DR. MANAKER: I'll just say I'm against
16 moving it.

17 DR. HAMBRICK: Got you.

18 And it was seconded. Discussion? One
19 against? Any further discussion?

20 DR. MANAKER: Yeah. I mean, I would just
21 say it's going to be billed multiple times, so I
22 don't see moving it until there's more cost data

1 available.

2 DR. HAMBRICK: More discussion?

3 All those in favor of moving it for the
4 motion -- all those in favor of the motion, please
5 indicate by saying aye.

6 (Simultaneous ayes)

7 Opposed, nay.

8 DR. MANAKER: Nay.

9 MR. O'BRIEN: Nay.

10 DR. HAMBRICK: Did everybody vote? I
11 counted like seven people.

12 Were there abstentions? Maybe that's
13 why.

14 Let's do it again. All those in favor
15 say aye.

16 (Simultaneous ayes)

17 Opposed, nay.

18 DR. MANAKER: Nay.

19 MR. O'BRIEN: Nay.

20 DR. HAMBRICK: Ayes have it.

21 Now, let's review. Does anyone, any
22 panel member -- thank you very much for your

1 presentation.

2 Does any panel member wish to make any
3 recommendations on any of the other presentations
4 that we've heard before? Okay. So, this concludes
5 this portion of the meeting. I'm sorry.

6 MS. ARTIGUE: Dr. Hambrick, I'm sorry. I
7 had my hand raised. I apologize.

8 DR. HAMBRICK: Oh, sorry. I see it now.
9 Go ahead, Ms. Artigue.

10 MS. ARTIGUE: That's okay. I'd just like
11 to go back to the wound care stakeholders
12 presentation.

13 DR. HAMBRICK: Okay.

14 MS. ARTIGUE: And see if we can review
15 the total contact case. And so --

16 DR. HAMBRICK: Okay.

17 MS. ARTIGUE: -- in support of their
18 recommendation, I would like to propose or make a
19 recommendation that CMS move the status indicator on
20 CPT code 29445, application of rigid total contact
21 leg cast, to status indicator S.

22 DR. HAMBRICK: Is there a second?

1 DR. TETTELBAACH: I second.

2 DR. HAMBRICK: Okay. Discussion?

3 DR. LEVIN: So, I'll just put my hand
4 here. Are we also going to say that -- remind me. I
5 think that I had some notes here.

6 I think that part of the discussion was
7 whether we were going to consider that to be a wound
8 bandage and, therefore, not separately reportable or
9 whether we were going to change the APC for it.

10 DR. TETTELBAACH: No, this is for the
11 total contact cast.

12 MS. ARTIGUE: Right.

13 DR. TETTELBAACH: The total contact cast
14 is offloading, which is a gold standard, as mentioned
15 in the presentation. The problem is that it's
16 bundled into almost every procedure, so you can't
17 debride and then put it on.

18 So, the patients -- because the clinics,
19 be it HOPD, will -- don't make -- lose money. You
20 know, they can't sustain it.

21 MS. ARTIGUE: Right.

22 DR. TETTELBAACH: Or they ask the patient

1 to come back another -- like the day after or
2 something, which is like this huge burden on the
3 patient. So, again, this is Bill Tettelbach.

4 So, separating these out would actually
5 allow for the standard of care to occur within the
6 HOPD clinics, which doesn't happen right now.

7 DR. LEVIN: And I know that we're not
8 here to discuss CPT, but they are actually separately
9 reportable between the 11042 and the total contact
10 cast.

11 MS. ARTIGUE: That is correct. Coding
12 clinic allows that separate reporting. So, what the
13 group asked and what I'm suggesting is that instead
14 of it being reimbursed at 50% with status indicator
15 T, that we move it to status indicator S and have it
16 reimbursed as a separate procedure.

17 DR. TETTELBAACH: Yeah.

18 DR. LEVIN: Yeah. I'll --

19 DR. TETTELBAACH: Yeah. Because all that
20 will happen is that they'll just ask them to come
21 back, they'll put it on the day after, and it gets
22 reimbursed and it just -- you know, like it's better

1 to do it all in one shot.

2 MS. ARTIGUE: Of course. Beneficiary
3 access and, you know, convenience.

4 DR. TETTELBACH: Yes, exactly. So, I
5 second it.

6 DR. HAMBRICK: All right. Further
7 discussion on the motion?

8 All those in favor signify by saying aye.

9 (Simultaneous ayes)

10 Opposed, nay.

11 Abstentions?

12 Motion carries.

13 Any other presentation that a panel
14 member would like to make a recommendation about?

15 Okay. All right. Then what we'll do is
16 we will -- keep your cameras and stuff -- I mean,
17 keep your computers and all that on.

18 We'll recess for -- Ms. Muzquiz, how long
19 do you think that it will take you to compile the
20 summary recommendations? About 30 minutes? Tell us.

21 THE TRANSCRIPTIONIST: Yes, 30 minutes
22 will be good.

1 DR. HAMBRICK: Okay. So let's go with 30
2 minutes. Let's see what time it is. So, everybody
3 come back at 2:48 and we'll see if we have the
4 recommendations. If not, take your time. It's more
5 important to be accurate than, you know.

6 Ms. Muzquiz, be nice to her, this is her
7 first meeting with us, and we'll want her to come
8 back. So I'll see everybody at 2:48.

9 (Session is in recess at 2:18 p.m.)

10

11 (Session resumes at 3:15 p.m.)

12

13 MS. CESNIK: Edith, do you want me to go
14 ahead and share the recommendations?

15 DR. HAMBRICK: Yeah, if you could send it
16 out to the panelists, I'd appreciate it. Thanks.

17 MS. CESNIK: Yes.

18 Okay. Panelists, you should be receiving
19 that shortly.

20 Edith, should I go ahead and share my
21 screen?

22 DR. HAMBRICK: Let them get the

1 recommendations first.

2 MS. CESNIK: Okay.

3 DR. HAMBRICK: So, the panelists can
4 just, you know, thumbs up or whatever.

5 MS. CESNIK: Actually, Karen, I'm not
6 seeing where I'm supposed to press to share my
7 screen.

8 DR. SETH: Did you send the email?

9 MS. CESNIK: Yes. Yes, it should be --

10 MS. MOHR: Okay. It should be at the top
11 ribbon, and share screen is all the way over to the
12 right-hand side.

13 MS. CESNIK: Oh, okay, I see it now.
14 Thank you.

15 And it should be -- and, yes, I've
16 emailed it. It should be my -- I apologize. My
17 email has been sending things -- sending things out
18 slowly, but you should be receiving it shortly.

19 DR. SETH: I got it. Thank you.

20 DR. MANAKER: Yep, just popped up.

21 MS. CESNIK: Perfect.

22 DR. HAMBRICK: Everybody got them? Panel

1 members, that is.

2 MS. SMITH-LLOYD: I got them. Yes, I
3 did.

4 MR. DIRKSEN: Yep.

5 DR. HAMBRICK: Okay. So for the public,
6 we will display these, but we ask that you, you know,
7 not take any pictures or anything like that, because
8 we're in the process of, you know, discussion. The
9 final recommendations will be posted to the website
10 in a few days, weeks.

11 Okay, here we go. So, we're just going
12 to scroll down as we usually do, and then stop us if
13 there's something that looks awry, especially the
14 makers of the motion and the seconders.

15 Okay. So the first one is about the
16 endobronchial valve procedure.

17 Number two is about the major depressive
18 disorder treatment presentation.

19 Number three is about the total contact
20 cast.

21 Number four is about the gastric
22 electrophysiology mapping procedure.

1 Five is about the radiation treatment
2 software and planning, planning software.

3 DR. MANAKER: Edith. Edith?

4 DR. HAMBRICK: Yes.

5 DR. MANAKER: There's no problem with the
6 recommendations, but between two and three, shouldn't
7 it be -- shouldn't there be a bolded title "APC
8 assignment for the tissue replacements"?

9 DR. HAMBRICK: Yeah.

10 MS. CESNIK: Yes, I'll add it in.

11 DR. HAMBRICK: That will be an amendment.
12 We'll type that in.

13 DR. TETTELBACH: Yeah, APC assignment for
14 a total contact cast, maybe, because there's no
15 tissue.

16 DR. HAMBRICK: It's really a status
17 indicator change, right?

18 MS. ARTIGUE: Yes.

19 DR. HAMBRICK: Otherwise --

20 DR. MANAKER: Say again, Edith, I
21 couldn't hear.

22 DR. HAMBRICK: I just said, it looks good

1 otherwise, for all the --

2 DR. MANAKER: Yes. Yes, otherwise looks
3 fine.

4 MS. ARTIGUE: Yes, that is fine.

5 DR. HAMBRICK: Okay. Then I'll entertain
6 a motion for approving the minutes.

7 DR. MANAKER: Move.

8 DR. SETH: I'll move it second.

9 DR. HAMBRICK: Okay. All right. I think
10 we got down to Ms. Artigue, how can we not get down
11 to you? Okay.

12 Any discussion or other changes?

13 DR. MANAKER: Nope.

14 DR. HAMBRICK: Especially if we're going
15 in alphabetical order, Dr. Hambrick.

16 DR. HAMBRICK: Yes, I know. Zeller's up,
17 Dr. Zeller's up next. We'll start in alphabetical
18 order next time.

19 All those in favor, indicate by saying
20 aye.

21 (Simultaneous ayes)

22 Opposed, nay.

1 And any abstentions?

2 I want to thank all the participants
3 today, the presenters, the attendees, OPPS staff, and
4 managers, our DFO, Abby Cesnik, because we had some
5 little issues today, our transcriber, Natasha
6 Muzquiz, and Ms. -- I knew I murdered your name, and
7 our moderator, Ms. Karen Mohr, and all of the
8 panelists who make it work.

9 We'll see you again, some of you, maybe
10 more of you, next year. Take care. The meeting is
11 adjourned. Thank you.

12 (Whereupon, at 3:22 p.m., the meeting was
13 adjourned.)

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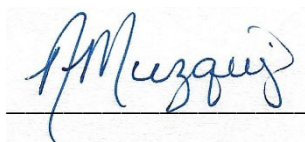
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C E R T I F I C A T E

I, Natasha A. Muzquiz, do hereby certify that I transcribed the foregoing proceedings of the Advisory Panel on Hospital Outpatient Payment Meeting, held August 24, 2026, from the audio recording provided by the Centers for Medicare & Medicaid Services and from my own contemporaneous audio recording of the proceedings.

I further certify that the foregoing is a true, accurate, and complete verbatim transcript of said proceedings to the best of my knowledge and ability.

I further certify that I am not related to, employed by, or otherwise associated with any member of the Panel, any presenter, or any entity whose test codes were considered at this meeting, and that I have no financial or other interest in the outcome of the Panel's recommendations.

A handwritten signature in blue ink, appearing to read "Natasha A. Muzquiz", is written over a horizontal line.

Natasha A. Muzquiz, CET