



September 30, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1734-P; CY 2021 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 17, 2020)

Dear Administrator Verma,

The American Society of Plastic Surgeons (ASPS) is the world's largest association of plastic surgeons. Our over 7,000 members represent 93 percent of Board-Certified Plastic and Reconstructive Surgeons in the United States. ASPS promotes not only the highest quality in patient care, but also in professional and ethical standards. Our members are highly skilled surgeons who improve both the functional capacity and quality of life for patients, including treatment of congenital deformities, burn injuries, traumatic injuries, hand conditions, and gender affirmation surgery. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (Proposed Rule) on the revisions to Medicare payment policies under the Physician Payment Schedule for calendar year (CY) 2021, published in the August 17, 2020 Federal Register (Vol. 85, No. 159 FR, pages 50074-50665).

This Proposed Rule includes several provisions that, if enacted, will have negative consequences for our members and the patients they serve. In this letter, we offer comments on the following provisions:

- I. 2021 proposed conversion factor
 - a. E/M visits in the global surgery period
- II. Comment solicitation on the definition of HCPCS code GPC1X
- III. Telehealth and other services involving communication technology
- IV. Valuation of specific codes
- V. Appropriate Use Criteria

I. <u>Conversion Factor</u>

The Centers for Medicare & Medicaid Services (CMS) has implemented policies that will reduce the Medicare CY 2021 conversion factor from \$36.0896 to \$32.2605, or by 10.6 percent, due to statutory budget neutrality restrictions. The Agency indicates that this reduction mostly stems from new spending resulting from implementation of changes to the office/outpatient evaluation and management (E/M) services and related codes and policies. Refinements to reduce documentation of these services was supported across the House of Medicine, and while we concur with the CMS decision to accept a portion of the AMA's Relative Value Update Committee (RUC) recommendations that provided an increase as a whole to E/M codes, we believe that CMS has fallen short both by failing to accept the entire package of recommendations (that were formed as a coherent whole) and by injecting extraneous policies into a set of recommendations that were thoughtfully developed and broadly endorsed by the House of Medicine. We respectfully remind CMS that payment reduction does not equal payment reform. We are extremely concerned that because of budget neutrality requirements, the Agency is proposing a conversion factor decrease that has a negative redistributive effect on some but not all physicians in the midst of a public health emergency (PHE).

For the last seven months healthcare providers have struggled with the financial impact of the COVID-19 pandemic in many ways, including salary reductions, furloughs, and layoffs. The cancellation of elective surgeries and services at the onset of the pandemic was especially impactful on Plastic and Reconstructive Surgeons. We also call your attention to a recent survey undertaken by the Surgical Care Coalition, of which ASPS is a part, showing that about one-third of private surgical practices were already at risk of closing permanently due to the financial strain of the COVID-19 crisis and noted "This rule will likely force surgeons to take fewer Medicare patients, leading to longer wait times and reduced access to care for older Americans."

a. E/M visits in the Global Surgery period

We note that over \$194,000,000 of the spending increases and resulting conversion factor reduction is attributed to a CMS proposal to increase valuation for Initial Preventive Physical Exam and Annual Wellness visits (codes G0402, G0438 and G0439). To our knowledge, these codes have never been subject to a review by the RUC to confirm their relative value within the fee schedule; however CMS has determined they are eligible for adjustment of their valuations commensurate with changes made to the values for office/outpatient E/M visits due in part to their initial valuation via a crosswalk to existing E/M services.

In contrast, we note CMS fails to extend a similar commensurate increase to separately identifiable visits occurring during the surgical global period, in part due to statements by the Agency about concerns related to the valuation of these services. As an active member of the RUC, we remind CMS that since January 2014, over 3,700 90-day global codes have been extensively scrutinized by the RUC, including both the number, as well as the "level" of the of post-op visits. In January 2010, the RUC voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10 or 90-days.

https://www.surgicalcare.org/wpcontent/uploads/2020/06/SCC Member Survey Data 06172020 FINAL.pdf

As such, we are puzzled as to why the Agency is ignoring these recommendations and instead continues to state its concerns with the valuation of services in the post-operative period without providing any new data to support its claim. ASPS feels strongly that it is inappropriate for CMS to rely on the related provision in the Medicare Access and CHIP Reauthorization Act (MACRA), which passed in 2015 and encouraged a review of the services provided in the global period, as a reason to refrain from making necessary updates to surgical globals in 2021. While CMS has on multiple occasions attempted to analyze global billing, a continued lack of attention and action by the Agency is further punishing a subset of physicians who, like all healthcare practitioners, are experiencing the pressures of a global pandemic.

ASPS members are committed to providing the highest quality of care to our patients but fear a 10.6% cut to the conversion factor paints a dire picture for the independent physician practice's future and will have a significant impact on beneficiary access to reconstructive services, especially in rural and underserved areas, making it more difficult for our patients to obtain the quality cost-effective care they need. We urge the Agency to explore all avenues, including working with Congress, to prevent drastic cuts from occurring while physicians are still trying to recover and gain their financial footing from the effects of the pandemic.

Additionally, we urge CMS to incorporate the full increase of work and physician time for office visits into the global periods for each CPT code with a global period of 10 or 90-days. Not only is it the most thoughtful, appropriate policy to maintain the relativity of the fee schedule, but not doing this is ignoring the Agency's precedent set *three times* when E/M codes experienced significant revaluations (1997, 2007, and 2011) and the Agency ensured the relativity between E/Ms and globals was maintained.

II. GPC1X

In this proposed rule, CMS is seeking public comments on what aspects of HCPCS add-on code GPC1X are unclear, how they might address those concerns, and how they might refine utilization assumptions for the code. The Agency first introduced a version of this code as part of CY 2019 rulemaking where the Agency's stated rationale was that the code was "to recognize additional relative resources for primary care visits and inherent visit complexity that require additional work beyond that which is accounted for in the single payment rates for new and established patient levels 2 through level 5 visits." Then, when the Agency eliminated the proposal to collapse the E/M code visit levels, the Agency reintroduced this code and finalized it in the CY 2020 MPFS Final Rule, under a different rationale, now stating it was because it felt the revised E/M code set did not adequately describe or reflect the additional resource costs inherent in furnishing some kinds of E/M office visits, including patient education, expectations and responsibilities, and shared decision making. At that time, the Agency used the "crosswalk" methodology to assign a wRVU of 0.33 for this service and estimated the utilization across 21 specialties. In CMS's most recent utilization projections for add-on code GPC1X, CMS offered estimated utilization across 56 specialties, and assumes the code would be applied to 75% of all office visit claims, costing the Medicare program \$3.3 billion annually.

ASPS offers the following observations and comments in response:

- 1. The Agency itself is contributing to the confusion surrounding GPC1X in the way it describes this code in the Proposed Rule.
 - a. In Table 8, the code descriptor is listed as: Visit complexity inherent to evaluation and management associated with <u>primary medical care</u> services that serve as the continuing focal point for all needed health care services
 - b. In Table 24, the code descriptor is listed as: Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex chronic condition
- 2. By our count, there are over 80 Medicare Specialty Codes for healthcare providers who may provide E/M services and are recognized as part of the Medicare enrollment process. To ensure every healthcare provider understands the impact of their proposal, the Agency should immediately provide utilization as well as financial impact of GPCIX for all 80 specialties.
- 3. Additionally, CMS has failed to and must immediately provide clear reporting instructions and documentation guidelines for the reporting of this service as well as information on how this documentation will be reviewed and monitored. A lack of clear rules raises the risk that providers will be accused of fraudulent billing practices when audited through no fault of their own. At the very least, we urge the Agency to delay audits until instructions have been provided via Open Door Forums, Provider Calls, and other guidance and education mechanisms utilized by the Agency.
- 4. CMS should also work with EMR vendors to ensure necessary software updates can and have been completed before implementation of this proposal.
- 5. CMS should work with the RUC to validate, first, the necessity of this code and, if it is established that the code is defined well enough to value, then an accurate wRVU for this code.
- 6. Until such time that CMS has responded to all concerns, it should halt implementation of GPC1X. A delay would provide added time for a more thorough vetting and the establishment of guardrails to ensure appropriate usage.

Lacking completion of the all of the above, ASPS strongly objects to the implementation of GPC1X. We are gravely concerned the Agency is placing an added burden on the shoulders of providers who may not be able to bill this code to assume the cost associated with implementing it. This is in addition to the already significant payment reductions these same providers are facing due to CMS' other proposed payment policies and is untenable for the 62 percent of ASPS members who in private practice.

III. <u>Telehealth and other services involving communication technology</u>

Telehealth provides an alternate pathway for conducting patient visits, and we appreciate the Agency's willingness to engage in a discussion regarding the differing communication technologies employed during the pandemic. The waivers issued by CMS have been beneficial to patients across the country

and telehealth has become a vital tool for Plastic Surgeons, improving patient access to health care during this pandemic.

ASPS supports the proposal to make permanent communication flexibilities by allowing coverage and reimbursement for audio-only E/M. As discovered during the PHE, it is often challenging to establish a synchronous telemedicine connection defined as "live, two-way audiovisual link between a patient and a care provider" with patients. While there certainly are circumstances which necessitate in-person interaction to determine the current health status of the patient; for established patients, however, clinical decision-making and care planning is well-informed based on the existing relationship and information documented in the medical record. In particular, telephone E/M has been a vital lifeline allowing Medicare beneficiaries access to needed E/M services while allowing them to stay safe at home during the PHE. ASPS believes the need for appropriate coverage and reimbursement of telephone E/M will not end on the date the PHE is declared over. Access to telephone E/M will continue to be necessary at least through the year in which the PHE is declared to be over.

As such, ASPS encourages CMS to continue to allow communication flexibilities, including audio-only E/M visits for Medicare patients, to be an available and fully reimbursed option for CY 2021, and respectfully request the Agency pay for audio only services at the same rate as services provided face-to-face or via interactive telecommunication technology.

Additionally, we encourage CMS to ensure that physicians and health care professionals delivering telemedicine services are in full compliance with the state licensure and medical practice laws where the telehealth services are being delivered. ASPS supports preserving direct supervision that allow physicians to supervise in-office clinical staff using communications technologies, when appropriate. We believe that scope of practice laws should be applied the same for telemedicine services as they are for in-person services to not undermine the physician-centered, team-based healthcare delivery model.

IV. Valuation of specific codes

We appreciate the opportunity to provide input on the valuation of 10 codes that relate to breast surgery and/or breast reconstruction and one code related to tissue expansion that was part of the associated AMA CPT Editorial Panel/RUC process. As the Agency is well aware, the time and effort taken to shepherd codes through the AMA process can be extensive. As such, we are extremely disappointed in the significant changes CMS has made to proposed work RVU valuations proposed by CMS for these codes often without an in-depth explanation.

While our society may not always agree with the recommendations of the RUC, we are fully supportive of the extensive amount of time and effort that was spent in reviewing all of the available data provided via the survey process as well as the expertise and consultative services of the RUC Panel to arrive at recommendations that are consistent not just for these codes, but across the fee schedule. Specific to these codes, ASPS believes the RUC Panel used <u>ALL</u> of the survey data

to generate their recommendations, including, but not limited to, survey respondent recommended wRVU, comparison to Key Reference Codes, and surveyed times. In addition, for each of these codes, recommendations were made in comparison, not to a single code from a crosswalk after the decision on valuation was made, but in comparison to both MPC codes and recently valued codes (within the last 10 years) to ensure that valuations suggested by the survey were consistent with the current fee schedule. We believe the data presented to the RUC and used in a dedicated, intentional manner accurately reflect the appropriate valuation for these codes.

It is also important to note that the decision on code "families" for these codes was made in conjunction with the RUC in large part for administrative handling of a what was a significant section of the CPT book that actually contains codes that had previously not been consider related nor had they been considered a family in most other instances of RUC code valuation. In fact, some of the codes included in these tabs were actually in separate sections of the CPT book (i.e. integumentary vs breast) and would not have otherwise even been consider part of the same "family." With respect to this, we are significantly concerned about the use by CMS of incremental differences in the valuations for valuations within a family. This methodology might be applicable when codes have a clear, hierarchical relationship of complexity or a parent/child relationship. However, it is problematic when the codes are grouped administratively or have significant difference in work valuation. This methodology is also problematic because if an error is made in the valuation of the "first" or "base" code, then a systematic error is propagated through the remainder of the "family." It is especially concerning that the Agency states that "we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within family of similarly revised codes," and then uses this methodology both across different families of codes and within family that do not have similarly revised codes. This methodology has the appearance of crafting arbitrary values from the vast array of possible mathematical calculations, rather than seeking a valid, clinically relevant relationship that would preserve relativity.

And finally, we also have concern about the use of total time ratios compared to historical values. This is especially concerning when used for codes that were previously Harvard valued. While we understand that current times and values are considered "correct" unless compelling evidence is met, the utilization of times and values that are now over 25 years old when procedures and typical patients have changed may induce error into final recommendation. In addition, and as the RUC has also pointed out, the Harvard surveys included only overall post-operative time data. The times added for post-operative care were converted to E/M visits codes by a CMS contractor at a later date. We agree with the RUC that for these codes, "the first time survey data was collected on the number and level of post-operative visits, making comparison between historic Harvard times and modern RUC times precarious at best." Additionally, we respectfully remind CMS that for at least some of the codes related to breast surgery/breast reconstruction, the number of survey responses during the Harvard study was ten — a number that would fall well below the currently accepted minimum numbers for a valid survey.

Below are additional comments, specific to four of the "tabs" for breast reconstruction related codes.

(2) Tissue Expander Other Than Breast (CPT code 11960)

This code family was created due to the unique nature of 11960 not being related at all to breast surgery or breast reconstruction, but having been identified due to proximity with other codes used for breast reconstruction. Following a Code Change Application related to misuse of this code in carpal tunnel surgery, this code was surveyed due to a negative IWPUT and mis-valuation.

ASPS presented a valid survey of 31 plastic surgeons and agreed with the final RUC recommendation at the 25th percentile of a wRVU of 12.40. While a cross-walk for this code is difficult due to the number of outpatient post-operative visits compared to other codes with similar post-times due to inpatient visits, we presented comparison of this code to the closest two MPC codes (90 day global, IT 75-105, and TT 325-385) and at the recommend wRVU of 12.40, it would still be well below the other two codes (63047 – 15.37 wRVU and 37215 – 17.75 wRVU). In addition, when compared to other recently surveyed codes (RUC surveyed < 10yrs, 90 day global, IT=90, TT 327-387), at the RUC recommended wRVU of 12.40, this code would still rank 4th out of the 5 codes (range 12.38 to 17.48). Included in this comparison is the one, recently valued code, 65285 (wRVU 15.36), which has a similar number of post-operative clinic visits instead of inpatient time.

We disagree with the Agency's use of reference CPT code 45560 as a cross-walk. This reference code was last surveyed in August 2000 when the data presented to the RUC included using multiple modern, recently surveyed comparison codes that demonstrated an appropriate fit of the entire survey data with a RUC recommended wRVU at the 25th-percentile of the survey. In addition, CPT code 45560 has four inpatient days and only two outpatient days making comparison with CPT code 11960 more difficult.

We strongly disagree with Agency's comment that the "reduction in total time supports maintaining the current work value" when the previous time was potentially inaccurate due to Harvard methodology as noted in our introductory comments. As the Agency should be aware, this code previously had a negative IWPUT suggesting a mismatch in time and valuation, making any comparisons of time changes suspect, if not outright invalid. Finally, we note the CMS proposed value creates an IWPUT of 0.024, which is less than the IWPUT of a level 2 established office visit (currently 0.0346) despite the intensity of an invasive surgical procedure. For all these reasons, we urge CMS to accept the RUCs recommended wRVU value of 12.40 for CPT code 11960.

(3) Breast Implant-Expander Placement (CPT codes 11970, 19325, 19340, 19342, and 19357)

For this family of codes, we are concerned about the Agency's use of incremental differences based on the valuation of 11970 for the entire family. This logic is incorrect as the five codes in this family were

surveyed together as a family for administrative purposes and due to the fact that all included the conceptual similarity of placement of a breast implant or tissue expander. However, it should be noted that the range of current wRVUs within this family ranged from 8.01 to 18.50 suggesting significant differences in these procedures at baseline with the highest valued code over 200% the wRVU of the lowest code. This range of values would be rarely, if ever, seen in a traditional family of codes outside of add-on codes with a parent code. This difference in the family also necessitated two unique RSLs for the survey. Thus, the Agency's use of the incremental difference methodology is of significant concern among these codes.

In addition, we believe that errors in the Agency's proposed valuation of CPT code 11970 become systematic errors across the additional four codes when using an "incremental difference" methodology. We question if the Agency considered this when they opted to ignore recently valued codes as comparison codes for the majority of these codes. For the five codes in this tab, we also offer the following specific comments:

CPT code 11970 - Replacement of tissue expander with permanent Implant

ASPS presented a solid survey comprised of 43 plastic surgeons and proposed a wRVU of 8.01 which was current value and <u>well below</u> the survey 25% percentile value of 10.00. ASPS presented data to support how this code with a wRVU of 8.01 compared to similar MPC codes (MPC, 90 day global, IT 60, TT 200-230) ranking 2nd of 5 codes. In addition, when compared to recently surveyed codes in the last 10 years (last 10 years, 90 day global, IT 60, TT 200-230), the RUC recommended value of 8.01 fit well within the current code set ranking 11th out of 25 code (range wRVU 6.50-12.85).

We were disappointed to see the Agency chose to disregard the RUC recommendations and instead located a reference code that, while revalued in CY 2019, was supported by utilizing a "total time ratio." Of note this methodology was called out by the AMA in 2019 as an invalid process that does not treat all components of physician time as having identical intensity. The unintended consequences include the appearance of assigning "arbitrary values," to a code's work RVU that, in this case, are significantly lower than existing values. Moreover, CPT code 11970 was previously Harvard-valued making comparisons based on total time precarious, especially when compared to the *multiple* other data points used in the modern code set by the RUC to support the recommended value of 8.01.

The RUC agreed with these concerns and "noted that the current times for this service are over 25 years old from the Harvard study and not valid for comparison. The IWPUT 0.041 for the current times is inappropriately low for this relatively intense major surgical procedure, which strongly implies the current times are inflated relative to the current work RVU and not valid for comparison to the new times."

We respectfully remind the Agency that one out of eight women are diagnosed with breast cancer in their lifetime. A national policy on reimbursement for breast cancer reconstruction was created to *encourage* reconstructive services in the Women's Health and Cancer Rights Act of 1998. Using arbitrary values to lower reimbursement will, negatively impact access to reconstructive care and will, we fear, disproportionally impact access for women of color.

Thus, we are supportive of the RUCs recommendation to use all available data which supported the recommended wRVU value of 8.01 for CPT code 11970 and urge CMS to adopt this valuation rather than their proposed value.

<u>CPT code 19325</u> – <u>Breast augmentation with implant</u>

ASPS presented a solid survey of 45 plastic surgeons, seeking the current value of 8.64 wRVU which was *below* the survey 25th percentile value of 10.00 wRVUs.

During the RUC meeting, ASPS shared data to support a wRVU of 8.64 specifically, the comparison to similar MPC codes (MPC, 90 day global, IT 50-70, TT 205-245) ranking 3rd of 10 codes with a range of 6.36-9.77). In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 60, TT 60, and TT 215), the RUC recommended value of 8.64 fit well within the current code set ranking 5th out of 16 codes (range wRVU 6.55-12.85). It is important to also note that within this range of codes, seven of the codes lower than the recommend value are all from the same soft tissue excision family which skews the rank order.

The RUC rationale also "noted that the drop in intra-service time and total time does not necessarily warrant a change in value for the survey code. The RUC noted that the current times for this service are over 25 years old from the Harvard study and not valid for comparison. The IWPUT 0.052 for the current times is low for this relatively intense major surgical procedure, which strongly implies the current times are inflated relative to the current work RVU and not valid for comparison to the new times."

In its review, CMS noted the relative difference in work between CPT codes 11970 (*Replacement of tissue expander with permanent Implant*) and 19325 is equivalent to the RUC-recommended interval of 0.63 RVUs, and disregarding the RUC recommendation, proposing instead a wRVU of 8.12. As previously outlined, we have concerns about the incremental difference methodology especially considering our objections over the Agency's derivation of the propose value for CPT code 11970 as outlined above. Furthermore, the Agency is referencing a comparison code last valued over 18 years ago to support the methodology instead of looking at the range of recently valued codes which support the total available data used by the RUC.

Thus, we have significant concerns with the methodologies used by CMS and strongly encourage the adoption of the RUCs recommended wRVU value of 8.64.

CPT code 19340 – Insertion of breast implant on same day of mastectomy (i.e., immediate)

ASPS presented a survey of 44 plastic surgeons with a recommend wRVU of 12.00 which was <u>below</u> the 25th percentile wRVU of 14.25. A review of codes surveyed in the last 10 years with similar intra and total time revealed eight codes, with all but two valued lower than our recommended value of 12. Ultimately, this code was handled through the RUC facilitation process and approved at a wRVU recommendation of 11.00 based on an additional crosswalk code of 36831 (Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure). It is important to also note that limited possible crosswalk codes were available for the surveyed times during the facilitation session.

Review of Key Reference Codes from the survey demonstrates that even at a wRVU of 11.00, CPT code 19340 is much lower in comparison to code 19303 (Mastectomy, simple, complete – wRVU 15.00) despite very similar times and nature of work since both involve surgery on the breast. It is important to note that this comparison procedure is something directly related and understood by plastic surgeons who not only perform this procedure occasionally but are clearly familiar with in the combined treatment of our breast cancer patients.

Using the RUC recommended wRVU of 11.00, this value when compared to similar MPC codes (MPC, 90 day global, IT 75-85, TT 250-310) would rank 3rd of 7 codes with a range of 9.37-15.00. In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 75-85, TT 270-290), the RUC recommended value of 11.00 fit well within the current code set ranking 3rd out of 9 codes (range wRVU 8.85-17.40). It is important to also note that within this range of codes, all of the additional codes had only 75 minutes of intra-time compared to the accepted intra-time of 80 minutes for 19340. In addition, all six of the codes with lower wRVU are from the same family (soft tissue excision codes) which skews the rank order.

In its review, CMS noted the relative difference in work between CPT codes 19325 (Breast Augmentation) and 19340 is equivalent to the RUC-recommended interval of 2.63 RVUs, and disregarding the RUC recommendation, proposing instead a wRVU of 10.48. As previously outlined, we have concerns about the "incremental difference" methodology especially with our concerns about the derivation of the proposed value for 11970 as outlined above which, in turn, was used to support the Agency proposed value for 19325. Furthermore, the Agency is referencing a comparison code, CPT code 47562, last valued 15 years ago to support the methodology instead of looking at the range of recently valued codes which support the total available data used by the RUC.

Rather than the arbitrary methods it appears the Agency has used; we urge CMS to instead support the recommended wRVU value of 11.00.

<u>CPT code 19342</u> – <u>Insertion or replacement of breast implant on separate day from mastectomy</u>

ASPS presented a survey of 43 plastic surgeons with an initial recommendation to maintain the current wRVU of 12.63 which was *below* the 25th percentile wRVU of 14.38. Ultimately, the

recommendation from the Society and RUC following facilitation was a recommended wRVU of 11.00. This value was based on direct comparison to the similarity in times and work of 19342 compared to 19340 which was valued at the same facilitation session using cross-walk, CPT Code 36831 (Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure). It is important to also note that limited possible crosswalk codes were available for the surveyed times during the facilitation session.

Using the RUC recommended wRVU of 11.00, this value when compared to similar MPC codes (MPC, 90-day global, IT 75-85, and TT 232-272) would rank lowest of 3 codes with the other two MPC codes having wRVUs of 11.90 and 13.16 respectively. In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 75-85, TT 232-272), the RUC recommended value of 11.00 fit well within the current code set ranking 5th out of 10 codes (range wRVU 9.29-13.16).

In its review, CMS noted the relative difference in work between CPT codes 19325 (Breast Augmentation) and 19342 is equivalent to the RUC-recommended interval of 2.63 RVUs, and disregarding the RUC recommendation, proposing instead a wRVU of 10.48. As previously outlined, we have concerns about the incremental difference methodology especially with our concerns about the derivation of the proposed value for 11970 as outlined above which, in turn, was used to support the Agency proposed value for 19325. Furthermore, the Agency is referencing a comparison code, CPT code 47562, last valued 15 years ago to support the methodology instead of looking at the range of recently valued codes which support the total available data used by the RUC. The Agency also noted the decrease in times associated with this code, ASPS noted then, and respectfully reminds the Agency now that 19342 was Harvard valued, and during the initial Harvard study only overall post-operative time was surveyed. Data on the number and level of hospital and office post-operative visits were not collected. Instead, a CMS contractor "converted" the overall time to E/M visit codes using an algorithm some years after the original Harvard study.

Again, rather than the inconsistent methodology it has used, we implore the Agency to instead support the recommended wRVU value of 11.00.

<u>CPT code 19357</u> - <u>Tissue expander placement in breast reconstruction, including subsequent expansion(s)</u>

ASPS presented a survey of 44 plastic surgeons who indicated a 25th percentile wRVU of 17.95. This value recognizes the complexity of the post-operative visits which are themselves, procedural in nature. Through facilitation, the RUC located an additional crosswalk code, CPT code 65285 (*Repair of laceration; cornea and/or sclera, perforating, with reposition or resection of uveal tissue*) and approved a recommended 15.36. The ability to identify crosswalk codes for 19357 is difficult due to the extensive amount of post-time for the tissue expander fills compared to the intra-time with very few codes having this ratio of intra-time to post-time. The RUC also supported this recommended

wRVU with comparison to MPC code 19303 (*Mastectomy, simple, complete*) which has significantly less total time as well as to the earlier valued 11960 (*Tissue expander, other than breast*) which is less intense.

Using the RUC recommended wRVU of 15.36, this value when compared to similar MPC codes (MPC, 90-day global IT 75-105, and TT 333-393) would rank lowest of 3 codes with the other two MPC codes having wRVUs of 15.37 and 17.95 respectively. In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 90, TT 333-393), the RUC recommended value of 15.36 fit well within the current code set ranking 4th out of 5 codes (range wRVU 12.38-17.48).

CMS disregarded the RUC recommendation and instead chose to propose a value that they believe is equivalent to the RUC-recommended interval between this code and 11970 (Replacement of tissue expander with permanent Implant). As previously outlined, we have concerns about the "incremental difference" methodology especially with our concerns about the derivation of the propose value for 11970 as outlined above. Even more concerning is that the interval difference is 7.35wRVU which is *almost double* the Agency proposed value for 11970 at baseline. This significant difference in the procedures raises further concern about the validity of the incremental difference methodology especially when wRVU values are so disparate. Furthermore, we are puzzled by the Agency's choice of a comparison code, CPT Code 37605 (Ligation; internal or common carotid artery) last valued over 19 years ago to support the methodology instead of looking at the range of recently valued codes which support the total available data used by the RUC. This comparison code also does not have a similar distribution of post-operative times between the inpatient and outpatient setting especially compared to more recently valued codes that are available for comparison.

Based on these observations, we petition CMS to support the recommended wRVU value of 15.36.

(4) Breast Implant-Expander Removal (CPT codes 11971 and 19328)

CPT code 11971 - Removal of tissue expander without insertion of permanent implant

The ASPS survey of 56 plastic surgeons indicated a 25th percentile wRVU of 7.02 which was ultimately the recommend wRVU by the RUC. Using the RUC recommended wRVU of 7.02, this value when compared to similar MPC codes (MPC, 90 day global, IT 40-50, TT 204-264) would rank 2nd of 4 codes (range 5.86-7.07). In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 45 TT 214-254), the RUC recommended value of 7.02 fit well within the current code set ranking 2nd out of 4 codes (range wRVU 6.76-8.38). For both of these comparison groups, it is important to note that the percentage of patients requiring at least an overnight hospitalization is significantly higher than any of the comparison code, but it is not otherwise reported physician work due to the global period. This increased post-operative care, that is otherwise not accounted for, was supported by both the physician survey and review of RUC data base claims. The survey reported this

procedure was formed in a hospital 71% of the time with 30% of total patients staying overnight more than 24hrs with an additional 40% of patients staying overnight less than 24 hours (typically for antibiotics). This is supported as well by utilization from the 2018 RUC claims database which demonstrates 32.24% of patients had an inpatient hospital as a place of service and 52.24% had an outpatient hospital (on campus) place of service.

CMS disregarded the RUC recommendation and instead proposed a wRVU of 6.50, based on the RUC recommend interval between this code and 11970 (Replacement of tissue expander with permanent Implant). In addition to our previous articulated concerns about using the interval difference for valuation within a "family" of codes, the Agency elected to use this methodology now *across* families further questioning the validity of this methodology. Furthermore, the potential errors in valuation of 11970 can now be systematically attributed to a different family of codes. The Agency further supported their value with a comparison code 25671, which has slightly less total time, however this code was last reviewed by the RUC over 18 years ago and ignores the comparison to multiple recently valued codes. Finally, the Agency comments on the decreased times for this code compared to the previous survey in 1995, however, the previous negative IWPUT of -0.0401 suggest that the previous time/wRVU balance was already inappropriate making comparison of times alone problematic.

For these reasons, we believe CMS should accept the RUCs recommended wRVU value of 7.02 for CPT code 11971.

CPT code 19328 - Removal of intact breast implant

ASPS presented a survey of 56 plastic surgeons who indicated a 25th percentile wRVU of 7.44 which was ultimately the recommended wRVU by the RUC. Using the RUC recommended wRVU of 7.44, this value when compared to similar MPC codes (MPC, 90 day global, IT 40-50, TT 188) would rank highest of 4 codes (range 5.86-7.07). In addition, when compared to recently surveyed codes with similar times (10 years, 90 day global, IT 45 TT 203-233), the RUC recommended value of 7.44 fit well within the current code set ranking 4th out of 7 codes (range wRVU 6.74-8.38). For both of these comparison groups, it is important to note that the percentage of patients requiring at least an overnight hospitalization is significantly higher than any of the comparison code, but it is not otherwise reported physician work due to the global period. This increased post-operative care, that is otherwise not accounted for, was supported by both the physician survey and review of RUC data base claims. The survey reported this procedure was formed in a hospital 68% of the time with 29% of total patients staying more than 24hrs (typically for antibiotics). This is supported as well by utilization from the 2018 RUC claims database which demonstrates 13.04% of patients had an inpatient hospital as a place of service and 65.15% had an outpatient hospital (on campus) place of service. The RUC located an additional crosswalk code that supported our data, and approved wRVU of 7.44

CMS disregarded the RUC recommendation and instead, proposed a wRVU of 6.92 based on their comparison of this procedure to 11971 (Removal of tissue expander without insertion of permanent implant) and an interval difference of 0.42. Similar to our previously raised concerns about using the interval difference methodology, this use of this method related to code 19328 includes potential errors in the valuation of 11971 along with the errors in valuation of 11970 which was is the basis for the valuation of 11971. While we acknowledge the Agency's use of a recently valued comparison code, CPT code 28289, this is only one of a range of recently valued codes that can be used for comparison interchangeably. Thus, we support the RUC methodology of evaluating all of the available date and confirming that it fits within the current code set. Accordingly, we urge CMS to verify the RUCs recommended wRVU value of 7.44 for CPT code 19328.

(7) Secondary Breast Mound Procedure (CPT codes 19370, 19371, and 19380)

Each of the codes included in the secondary breast mound family underwent significant changes to the work descriptor to recognize work not previously described in the initial short descriptors. Additionally, the CPT and RUC Panels acknowledged the number of patients that are eligible for breast reconstruction has changed. Twenty or thirty years ago, patients would only be typically undergoing this procedure if the patient did not have a BMI over 30 nor any major comorbidities. Now, breast reconstruction is appropriately provided to a much broader patient population, including many more oncology patients, due to advancements in care and surgical technique over the past few decades. With the increased access to breast reconstruction, patients with more comorbidities require more complicated revisions to achieve a complete reconstruction matching the patient's expectations. The change in patient expectations has significantly increased the work intensity of these procedures not only intra-operatively, but also in the pre- and post- periods due to the elevated complexity of discussions with the patient. Additionally, we offer the following specific comments:

<u>CPT code 19370 - Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy</u>

The ASPS survey of 42 plastic surgeons indicated a 25th percentile wRVU of 10.00. Recognizing this was the first time the number and level of hospital and post-operative visits included in this code had been reviewed, the RUC approved a wRVU of 10.00, and located an additional crosswalk code to support this value. This recommend value compared to similar MPC codes (MPC, 90 day global, IT 70-85, TT 230-280) would rank 3rd of 5 codes (range 9.09-13.13). In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 70-85, TT 240-270), the RUC recommended value of 10.00 fit well within the current code set ranking 5th out of 7 codes (range wRVU 9.29-13.13).

CMS however, disregarded the RUC recommendation, and instead proposed to maintain the existing value of 9.17, which would be the below all recently surveyed codes with similar total and intraservice time. CMS supports their recommendation with the argument that the times have not significantly changed from the Harvard valuation and, thus, the wRVU should not change. However, we respectfully remind CMS that code 19370 now includes additional work and intensity not considered during the original Harvard valuation which would meet compelling evidence for an increase in valuation despite the similar times. While we understand that current times and values are considered "correct" unless compelling evidence is met, the utilization of times and values that are now over 25 years old when procedures have changed has, we believe, induced error in the Agency's recommendation. In addition, and as the RUC has also pointed out, in the Harvard surveys only overall post-operative time data was surveyed. The times added for post-operative care were converted to E/M visits codes by a CMS contractor. We respectfully remind CMS of the observations shared by the AMA RUC Panel that "the first-time survey data was collected on the number and level of post-operative visits, making comparison between historic Harvard times and modern RUC times precarious at best." For these reasons, we encourage CMS to adopt the recommended wRVU value of 10.00 for CPT code 19370.

<u>CPT code 19371 - Peri-implant capsulectomy, breast, complete, including removal of all intra-</u> capsular contents

ASPS surveyed_42 plastic surgeons, who indicated a 25th percentile wRVU of 10.81 for this service. Recognizing this was the first time the number and level of hospital and post-operative visits included in this code had been reviewed, the RUC approved a wRVU of 10.81, and located an additional crosswalk code to support this value. This recommend value compared to similar MPC codes (MPC, 90-day global, IT 90, and TT 240-280) would rank 3rd of 4 codes (range 9.37-13.36). In addition, when compared to recently surveyed codes with similar times (last 10yrs, 90 day global, IT 90, TT 251-271), the RUC recommended value of 10.81 fit well within the current code set 11th out of 11 code (range wRVU 10.81-15.00). Thus, this code at RUC recommended value is already **below all** recently valued codes with similar times.

CMS disregarded the RUC recommendation and proposed a wRVU of 9.88, based on their observation that the relative difference in work between CPT codes 19370 and 19371 is equivalent to the RUC recommended interval of 0.81 RVUs. We have already highlighted our concerns about this methodology within other families and note, the potential errors in the valuation of 19370 are now systematically included in the valuation of 19371. CMS supports their recommendation with the argument that the times have not decreased from the Harvard valuation. However, we respectfully remind CMS that code 19371 now includes additional work and intensity not considered during the original Harvard valuation which would meet compelling evidence for an increase in valuation despite the similar times. While we understand that current times and values are considered "correct" unless compelling evidence is met, the utilization of times and values that

are now over 25 years old when procedures have changed has, we believe, induced error in the Agency's final recommendation. In addition, and as the RUC has also pointed out, in the Harvard surveys only overall post-operative time data was surveyed. The times added for post-operative care were converted to E/M visits codes by a CMS contractor. Again here, we remind the Agency that for these codes, "the first-time survey data was collected on the number and level of post-operative visits, making comparison between historic Harvard times and modern RUC times precarious at best." The Agency offered a comparison code with the same intra-service time to support their proposal. However, CPT Code 25628 was last valued in 2007 and at that time had a recommend wRVU 11.00. CMS did not agree with this valuation and instead uses a value of 9.67. Using the CMS recommend wRVU, valuing 19371 at 9.98 would result in a value nearly 10% below the lowest recently valued code (63655 – wRVU 10.92) and 66% of the wRVU compared to highest recently valued code with similar times (29916- 15.00wRVU). Surely the Agency can agree it is problematic to use a crosswalk comparison that is not only older, but also which CMS and the RUC significantly disagreed on the valuation.

Thus, we are supportive of the RUCs recommendation to use all available data which supported the value of 10.82 and **urge CMS to revise their recommendations**.

<u>CPT code 19380 - Revision of reconstructed breast (eg, significant removal of tissue, readvancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)</u>

ASPS presented a survey of 41 plastic surgeons who indicated a 25th percentile wRVU of 12.00 for this service. Recognizing this was the first time the number and level of hospital and post-operative visits included in this code had been reviewed, the RUC approved a wRVU of 12.00 and located an additional crosswalk code to support this value. This recommend value compared to similar MPC codes (MPC, 90 day global, IT 100-140, TT 277-337) would rank lowest out of 5 codes (range 14.56-17.75). In addition, when compared to recently surveyed codes with similar times (last 10 years, 90 day global, IT 120, TT 287-327), the RUC recommended value of 12.00 fit well within the current code set ranking 8th out of 9 codes (range wRVU 11.00-15.68). Thus, this code at RUC recommended value is already below all MPC codes and the 2nd lowest of recently valued codes with similar times. The RUC concurred, approving a wRVU of 12.00. They also located an additional crosswalk code to support this value.

CMS disregarded the RUC recommendation and proposed a wRVU of 11.17, based on their observation that the relative difference in work between CPT codes 19371 and 19380 is equivalent to the RUC recommended interval of 1.19 wRVUs. We have already highlighted our concerns about this methodology within other families. In addition, the potential errors in the valuation of 19370 are now systematically included in the valuation of 19371 and further compounded in the valuation of 19380. The Agency offered a comparison code with the same intra-service time to support their proposal. While we are supportive of CMS using a more recently valued code, the proposed crosswalk and wRVU appears to be arbitrary, based on only one of 9 recently valued codes that

were available for comparison and does not take into account any of the additional information from the survey that was used by the RUC to determine a valuation which was then compared to the current code set for accuracy and fit.

As such, we have significant concerns with the Agency's proposal and **strongly recommend** adoption of the RUCs recommended wRVU value of 12.00 for CPT code 19380.

V. <u>Appropriate Use Criteria Program</u>

CMS does not address the Appropriate Use Criteria (AUC) program in the rule, which indicates the Agency plans to move forward with a January 1, 2021 start date. This program requires physicians to consult AUC using clinical decision support tools prior to ordering advance imaging services for Medicare beneficiaries, which is then appended to claims for those services. CY 2020 was to be an "Education and Operations Testing" period, however, the PHE has curtailed many providers from utilizing the testing, and we note a significant lack of feedback from CMS about best practices for those attempting to utilize AUC. This lack of education, coupled with our previously submitted comments on the administrative burdens of this program, are troublesome for ASPS. We encourage the Agency to extend the "Education and Operations Testing" period until mid-CY 2021 to ensure the success of this program and to immediately provide education on best practices for AUC.

ASPS appreciates opportunity to share our concerns regarding revisions to Medicare payment policies included in the CY 2021 Proposed Rule. This does not constitute the entirety of our comments however, as we will submit a separate letter addressing updates to the QPP and other quality-related provisions of this proposed rule. If you have any questions or need additional information, please contact Catherine French, APSS Director of Health Policy at 847.981.5401 or cfrench@plasticsurgery.org.

Sincerely,

Lynn Jeffers, MD, MBA, FACS

President, American Society of Plastic Surgeons

cc: Greg Greco, MD – ASPS Board Vice President - Health Policy/Advocacy Howard Levinson, MD – ASPS Board Vice President – Research Steve Bonawitz, MD – Chair, ASPS Health Policy Committee Jeff Kozlow, MD - Chair, ASPS Coding and Payment Policy Committee Ash Patel, MD - Chair, ASPS Healthcare Delivery Committee