



September 13, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244 –1816

Re: Comments on CMS-1751-P: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

On behalf of the Society of Gynecologic Oncology (SGO), I am pleased to submit comments in response to the proposed rule for the CY 2022 Medicare Physician Fee Schedule and Quality Payment Program (CMS-1734-P). SGO is the premier medical specialty society for physicians trained in the comprehensive management of gynecologic cancers in women. Our purpose is to improve the care of women with gynecologic cancers by encouraging research and disseminating knowledge, raising the standards of practice in the prevention and treatment of gynecologic malignancies and collaborating with other organizations interested in women's health care, oncology, and related fields.

Our comments address the following CMS proposals:

CY 2022 Updates to the Physician Fee Schedule

Changes to Practice Expense Inputs for Specific Services - Clinical Labor Pricing Update

Proposed Rule: CMS proposes to update the clinical labor pricing for CY 2022 in conjunction with the final year of the supply and equipment pricing update. Clinical labor rates were last updated in CY 2002 using Bureau of Labor Statistics (BLS) data and other supplementary sources when BLS data were not available. The update will again be based on BLS data. In most cases, the updated proposed rates are 50 percent more than their current value. Given these potential significant shifts in payment, CMS is considering the use of a 4-year transition to implement the clinical labor pricing update and seeks comment on this phased-in approach.

The SGO understands the need to update the clinical staff labor rates, which have remained unchanged for 20 years. However, due to the Medicare Physician Fee Schedule (MPFS) budget neutrality methodology, the proportional decrease in recognition of the costs of the other practice expense (PE) components, i.e., equipment and supplies, will have a devastating impact on physician specialists that perform procedures with high supply and equipment cost in their offices, such as screenings and biopsies for cancer diagnosis, cancer treatments, procedures to maintain dialysis access, and women health procedures.

For example, in a moderate sized gynecologic oncology practice on the outskirts of Philadelphia, approximately 45% of patients are insured through Medicare with the practice performing the following office-based procedures:

38505 Biopsy or excision of lymph node(s); by needle, superficial (e.g., cervical, inguinal, axillary)

49082 Abdominal paracentesis (diagnostic or therapeutic); without imaging guidance
 49083 Abdominal paracentesis (diagnostic or therapeutic); with imaging guidance
 56820 Colposcopy of the vulva;
 56821 Colposcopy of the vulva; with biopsy(s)
 57420 Colposcopy of the entire vagina, with cervix if present;
 57421 Colposcopy of the entire vagina, with cervix if present; with biopsy(s) of vagina/cervix
 57452 Colposcopy of the cervix including upper/adjacent vagina;
 57454 Colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix and endocervical curettage
 57455 Colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix
 57456 Colposcopy of the cervix including upper/adjacent vagina; with endocervical curettage
 57460 Colposcopy of the cervix including upper/adjacent vagina; with loop electrode biopsy(s) of the cervix
 57461 Colposcopy of the cervix including upper/adjacent vagina; with loop electrode conization of the cervix
 58110 Endometrial sampling (biopsy) performed in conjunction with colposcopy (List separately in addition to code for primary procedure)
 58555 Hysteroscopy, diagnostic (separate procedure)
 58558 Hysteroscopy, surgical; with sampling (biopsy) of endometrium and/or polypectomy, with or without D & C

The practice performed over 150 hysteroscopies with endometrial biopsy last year, over 50 LEEP biopsies, and over 80 paracenteses. When these procedures are done in the office, the patients can go home to their normal activities or back to work, with a much shorter period of recovery. When these procedures are performed in the hospital, patients typically need to take the entire day off because of the type of anesthesia used. Patients also pay significantly more as part of their copay for hospital-based procedures than they would for office-based procedures. The office has invested in the equipment and all the supplies and clinical staff needed to be able to perform these procedures in the office.

If the practice expense reimbursement for office-based procedures is decreased by 3- 10% per case, the office will not be able to cover the per case expenses for these procedures or recover their equipment investment. As a result, these cases will be transitioned back to the operating rooms at hospitals, increasing overall costs to Medicare and to the patients. Most hospital operating rooms are currently functioning at capacity and performing minor procedures in this setting would delay major cases that are only appropriately performed in a hospital setting.

To address the concerns described above, the SGO urges CMS to revisit the implementation of the proposed clinical staff labor update and make every policy attempt in the FY 2022 Final MPFS Rule to hold harmless specialty care while providing the much overdue clinical staff labor increases. With this in mind, we strongly encourage CMS to take the following actions:

- **Identify alternative BLS crosswalk labor categories for selected CMS PE labor staff types;**
- **Use the BLS median wage rate for updated pricing;**
- **Apply a fringe benefit multiplier of 1.296 in the calculation to update clinical labor rates;**
- **Phase-in the clinical labor rate update over four years; and**
- **Delay implementation of the update until CY 2023 after the final transition year of the update to supply and equipment items.**

Calendar Year 2022 Conversion Factor

Proposed Rule: CMS proposes to set the CY 2022 MPFS Conversion Factor at \$33.58. This represents a decrease of \$1.31, or more than 3%, from the 2021 Conversion Factor rate update of \$34.89. This 3.75% decline is due to a statutorily mandated budget neutrality adjustment (0.00%) to account for changes in work RVUs, the expiration of the 3.75% increase for services furnished in CY 2021 (as provided in the 2021 Consolidated Appropriations Act), and the CY 2022 RVU budget neutrality adjustment (-0.14%).

Updates to the conversion factor have consistently failed to keep up with inflation. The result is that the conversion factor is only about 50% of what it would have been if it had been indexed to general inflation as it was prior to

1998. The current budget neutral payment system has resulted in a 25% decrease in the investment in medical care provided by physicians in the last 20 years. Yet in this same timeframe, practice costs have increased due to several factors including implementation of electronic health records (EHRs), value-based care models and reporting requirements and the COVID-19 pandemic. Physicians face an unsustainable business model that threatens the viability of physician practices and patient access to surgical care as current gynecologic oncology practices may have as much as 50% of their patients with Medicare as their primary insurance. As we referenced above, further payment cuts in this current environment will simply force greater physician practice migration to large health systems leading to greater health system consolidation.

The SGO urges CMS to exercise the full breadth and depth of its administrative authority to avert or, at a minimum, mitigate these unconscionable payment cuts at a time when practices are still struggling under the weight of the pandemic. The SGO also urges CMS to work with Congress to address the budget neutral methodology of the MPFS that constrains necessary investments in medical care.

Evaluation and Management Services - Critical Care Visits

Proposed Rule: With respect to critical care visits, CMS proposes to 1) use American Medical Association Current Procedural Terminology (CPT) language as the definition of critical care visits; 2) allow critical care services to be furnished concurrently to the same patient on the same day by more than one practitioner representing more than one specialty; 3) allow critical care services to be furnished as split (or shared) visits; 4) disallow the billing of any other Evaluation and Management (E/M) visit for the same patient on the same date as a critical care service by the same practitioner, or by practitioners in the same specialty and same group to account for overlapping resource costs; and 5) disallow critical care visits to be reported during the same time period as a procedure with a global surgical period.

We support CMS adopting the CPT guidelines for the reporting of critical care services. However, we do not support the proposal to no longer allow physicians to report other Evaluation and Management (E/M) services on the same date as a critical care visit or during the same period as a procedure with a global surgical period. This is contrary to CPT specific instruction (CPT 2021 Professional, page 31) which states, “Critical care and other E/M may be provided on the same patient on the same date by the same individual.” **We urge CMS to reconsider this proposal. Although, not typical, instances occur where a patient may be seen on an inpatient floor, emergency department, or even a physician office and then later require critical care services on the same date or during a global surgical period. The SGO opposes these proposed restrictions on reporting critical care services. These are separate services and should be reported and paid.**

Evaluation and Management Services - Global Services

Proposed Rule: CMS proposes to maintain current payment policy that fails to incorporate the AMA RUC-recommended work and time incremental increases for the revised office/outpatient visit E/M codes into the 10- and 90-day global surgical package codes.

We believe it is inappropriate for CMS to maintain this current policy and not apply the RUC-recommended changes to global codes starting in CY 2022. Continuing this current policy will:

Disrupt the relativity in the fee schedule: Applying the RUC-recommended E/M value increases to stand-alone E/Ms, select global codes, and select bundled services, but not to the E/Ms that are included in the global surgical package will result in disrupting the existing relativity between codes across the MPFS. Changing the values for some bundled services that include E/M services, but not for others, disrupts this relativity, which was mandated by Congress, established in 1992, and refined over the past 27 years. Indeed, since the inception of the fee schedule, E/M codes have been revalued three times — in 1997 (after the first five-year review, in 2007 (after the third five-year review) and in 2011 (after CMS eliminated consult codes and moved work RVUs into the office visit codes). When the payments for new and established office visits were increased in these instances, CMS also increased the bundled payments for these post-operative visits in the global period. The Agency should apply a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies.

Create specialty differentials: Per the Medicare statute, CMS is prohibited from paying physicians differently for the same work, and the “Secretary may not vary the number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.” Failing to adjust the global codes is tantamount to paying some doctors less for providing the same E/M services, in violation of the law. In the CY 2021 MPFS proposed rule, CMS pointed to the method of valuation (i.e., building block vs. magnitude estimation) for a rationale as to why some bundled services should be increased in value to reflect the revised office/outpatient E/M values, while global codes should not. However, this statutory prohibition on paying physicians differently for the same work applies regardless of code valuation method. Therefore, the incremental increases should apply to all physicians.

Inappropriately rely on section 523(a) of MACRA: In the CY 2021 PFS proposed rule, CMS referred to its decision in the CY 2020 PFS final rule to not make changes to the valuation of the 10- and 90-day global surgical packages to reflect the increased values for the office/outpatient E/M visit codes while the agency continues to collect data on the number and level of post-operative visits included in global codes as required by MACRA. The MACRA data collection requirement, set forth in section 523(a), does not prohibit CMS from applying the RUC-recommended incremental increases to the office/outpatient E/Ms codes to global codes. In fact, section 523(a) specifically authorizes CMS to adjust surgical services, notwithstanding the mandate to concomitantly undertake the MACRA-mandated global code data collection project. In addition, it is inappropriate for CMS to rely on the implementation of MACRA, which passed in 2015, as a reason to refrain from making necessary updates. This inaction punishes a subset of physicians who, like all healthcare practitioners, are experiencing the pressures of a global pandemic as well as steadily rising costs of labor and supplies necessary to maintain a viable and safe practice.

Ignore recommendations endorsed by nearly all medical specialties: The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) in 2019 to recommend that the full incremental 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-day, 90-day, and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. In the CY 2021 PFS rule, CMS used the RUC recommendation as part of the rationale for increasing the values of the maternity services codes and select other bundled services, but then ignored the RUC’s advice by not applying the same logic to the global bundled codes.

In summary, we strongly urge CMS to apply the RUC-recommended changes to the E/M component of the global codes to maintain the relativity of the fee schedule. We support a fair and consistent policy for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies. We remain concerned with the RAND reports, which the Agency should not rely on to pay surgeons at a different rate than other physicians.

Telehealth

Proposed Rule: CMS is proposing to continue paying for services placed temporarily on the telehealth list in response to the COVID-19 public health emergency (PHE) through the end of 2023. CMS is proposing changes to implement a recent change to Section 1834(m), which removes geographic restrictions and permits the home as an originating site for telehealth services furnished for the purpose of diagnosis, evaluation, or treatment of a mental health disorder, so long as the practitioner has provided these services to the patient in person within the last 6 months. CMS is also proposing to revise its regulatory definition of “interactive telecommunications system” to permit use of audio-only communications technology for mental health telehealth services under certain conditions when provided to beneficiaries located in their home. During the PHE, CMS has allowed for the requirement for direct supervision to be met for diagnostic tests, physicians’ services, and some hospital outpatient services using virtual presence using real-time audio/video technology, instead of requiring a physician’s physical presence. CMS is seeking comment on whether this policy should be extended beyond the end of the PHE, and, if so, whether it should only be extended for a subset of services and whether these services would require a service level modifier.

The SGO strongly supports the proposal to extend coverage of services that were added to the Medicare telehealth list on an interim basis in response to the COVID-19 PHE until the end of 2023 and urges that it be finalized. We also recommend that the additional services added to the telehealth list during the COVID-

19 PHE, particularly the CPT codes for telephone E/M services (99441-99443), be included in the category of services which are proposed to remain on the telehealth list through 2023. These services have played a critical role in allowing physicians to continue to manage their patients' care while remaining at a safe physical distance from medical practice staff and other patients, as well as avoiding contact that can occur during transportation to and from medical appointments. It is critical that access to telehealth services continue beyond the PHE. Besides their use to manage care for patients with respiratory and other symptoms that could reflect COVID-19, telehealth is being used for patients with a variety of symptoms and acute and chronic conditions that can be evaluated and managed remotely. Provision of telehealth services to patients in their home or other location is a huge advantage for patients with mobility or functional impairments or other problems that make travel difficult, and it is preferable for immunocompromised patients and those with communicable diseases. Also, there are many areas of the country where in-person access to a gynecologic oncologist requires hours of driving and telehealth may be appropriate to triage the patient's issues. We firmly believe that determinations of when in-person care is necessary should be left up to the discretion of the treating physician.

We also urge CMS to continue covering audio-only E/M services through 2023 like the currently proposed Category 3 services. While not a high percentage of office visits were provided to Medicare patients via telehealth in 2020, access to audio-only services is critical for patients who do not have access to audio-visual telehealth services. Discontinuing payment for these services would exacerbate inequities in health care, particularly for those who lack access to broadband and/or audio-visual capable devices, including seniors in minoritized and marginalized communities where there were significant health disparities before COVID-19 that have become much worse during the pandemic. Broadband and audio-visual telehealth services are clearly not accessible by all Medicare patients.

With respect to direct supervision by interactive telecommunications technology, we believe the current policy during the COVID-19 PHE allowing "direct supervision" to include immediate availability through the virtual presence of the supervising physician using real-time, interactive audio/video communications technology should be made permanent. At a minimum, the current policy should be continued through 2023 as is proposed for Category 3 Medicare telehealth services. The fact that remote supervision may be inappropriate in some cases does not justify refusing to pay for it under any circumstance. In many rural and underserved areas patients may be unable to access important services if the only physician available must supervise or deliver services at multiple locations and may not be available to supervise services when all patients need them. Failure to allow remote direct supervision can mean that a patient would be unable to receive the service at all, rather than forcing in-person supervision to occur. Both patients and CMS rely on physicians' professional judgment to determine the most appropriate services to deliver, and the same principle should apply to how supervision is provided.

CY 2022 Quality Payment Program

Closing the Health Equity Gap in CMS Clinician Quality Reporting Programs

Proposed Rule Request for Information: In recognition of persistent health disparities and the importance of closing the health equity gap, CMS requests information on several CMS programs to make reporting of health disparities based on social risk factors, race, and ethnicity more comprehensive and actionable for hospitals, providers, and patients. Specifically, CMS is seeking comment on the potential future stratification of quality measure results by race and ethnicity, current data collection practices by hospitals to capture demographic data elements, and potential challenges facing clinicians with collecting a minimum set of demographic data elements in alignment with national data collection standards and standards for interoperable exchange.

We applaud CMS for seeking comment on ways to improve data collection to provide a better understanding of health disparities and their impact on access to care and patient outcomes. Disparities in access to genetic testing, preventive services, and other aspects of providing care for patients with gynecologic cancers are creating enormous inequities in outcomes and survivorship in our health care system, particularly for endometrial cancer and cervical cancer. Research is needed to help understand barriers to screening programs, discover new approaches to screening, and promote wider implementation of known strategies to facilitate optimal treatments and improved mortality for minority populations with these diseases. Collecting and reporting more comprehensive and

actionable data will represent an important step towards achieving health equity. The SGO supports the following recommendations to improve data collection in CMS quality reporting programs advanced by the American Medical Association and outlined in greater detail in their comment letter on this proposed rule.

- Dual-eligibility status should not be solely relied on when stratifying readmission or admission measures.
- Relying on algorithms for indirectly estimating race and ethnicity is not an appropriate solution. If CMS plans to use proxies for race and ethnicity data to help identify and address inequities in care delivery and health outcomes, it must be based on self-reported data.
- CMS must plan for situations where demographic data are limited or nonexistent; these plans must ensure physicians' payment, performance, or quality improvement metrics are not inappropriately impacted by choices patients make (e.g., resulting from small sample sizes or a lack of inhouse statistical expertise need to stratify performance data by demographic groups).
- CMS must consider and expect demographic data captured by certified health IT systems to vary by developer.
- CMS should coordinate with the Office of the National Coordinator for Health Information Technology (ONC) on health IT vendor policy levers to improve demographic data capture. These levers should not lead to physician burden or excessive costs.
- CMS should collaborate with ONC in the development of a voluntary certification program for certified electronic health record technology (CEHRT) that would enable physicians and health systems to adopt EHRs optimized for the collection of race, ethnicity, and primary spoken language data.
- It is premature to hold physicians and practices accountable for the collection and reporting of demographic data by race, ethnicity, and primary language, including through some sort of quality measure or tying it to an accountability program, such as the Merit-Based Incentive Payment System (MIPS).

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Thank you for the opportunity to provide comment and for your consideration. If the SGO can provide CMS with additional information regarding these matters, please do not hesitate to contact Pierre Desy, SGO Chief Executive Officer (CEO), at Pierre.Desy@SGO.org with questions or if SGO can provide additional information.

Sincerely,

S. Diane Yamada, MD
President