October 5, 2020

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1734-P
Room 445-G
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Re: Medicare Program; CY 2021 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (the "Proposed Rule")

Dear Administrator Verma:

The professional organizations below, representing an estimated 1.4 million physicians and non-physician practitioners throughout the country, strenuously object to the extraordinary budget neutrality (BN) reduction proposed by the Centers for Medicare & Medicaid Services (CMS) in the 2021 Medicare Physician Fee Schedule (PFS) proposed rule (the "proposed CF reduction"). While we support the CPT coding revisions and revaluations of office and outpatient evaluation and management (E/M) services recommended by the AMA/Specialty Society RVS Update Committee (RUC), we strongly oppose the proposed BN reduction proffered by CMS for these and other PFS changes proposed for 2021.

If adopted as proposed, the 2021 Medicare PFS will:

- Cripple the recovery of the nation's health care system by exacerbating revenue shortfalls that are already jeopardizing the financial viability of physician and non-physician providers across the country.
- Reduce access to medically necessary specialty services for those Americans who have delayed seeking specialty treatment due to the fear of contracting COVID-19.Institute a conversion factor that is only slightly more than half of the conversion factor applicable in 1994, adjusted for inflation. The anesthesia conversion factor would drop to a rate that is nearly the same as what was in place in 1991.
- Reduce Medicare payment for services provided in patients' homes, physician offices, non-physician practices, therapy clinics, skilled nursing facilities, hospitals and rehabilitation agencies — at a time when the spread of COVID-19 remains unchecked.
- Decrease lifesaving cancer screening services which now face significant backlogs. For example, screenings for breast cancer were down 90%, which will inevitably result in delays in diagnosis and treatment of this disease.
- Further exacerbate the problems occurring across the country with practices furloughing or cutting staff and an increasing number closing their doors. Of great concern is the impact that this will have on access to needed health care services, especially for beneficiaries in rural and underserved areas. Because, in the end, if these detrimental cuts are implemented, those who suffer the most will be patients.

- Implement poorly defined additional payments for complex care, the value of which is already incorporated into the updated E/M codes, which further exacerbates the budget neutrality reduction to the conversion factor.

Additional examples of the impact of the proposed payment rate reduction are set forth at Attachment A. In light of the ongoing impact of the pandemic on our ability to meet the needs of our patients, we strongly urge CMS to exercise its administrative discretion to eliminate or substantially mitigate the proposed BN reduction.

Preliminarily, we note that many of our objections to the proposed BN reduction were expressed last year, in response to CMS' proposed finalization of the E/M coding revisions and revaluations. In last year's PFS final rule, CMS provided repeated assurances that the medical community's concerns about the potential budgetary impact of the E/M changes and the community's suggestions for mitigating that impact would be taken into account once the budgetary impact of all proposed 2021 changes was calculated. Despite these assurances, the proposed rule fails to acknowledge the devastating impact of the proposed BN reduction, particularly in light of the already extraordinary financial stress placed on the nation's physicians and non-physician practitioners by COVID-19. CMS also fails to consider, nor does the agency address in the proposed rule, any of the numerous suggestions already offered by commenters to mitigate the budgetary impact of these changes in 2021. In fact, the proposed rule modifies the assumptions used to calculate the proposed BN reduction in a manner that exacerbates the budgetary problem noted by commenters last year.[1]

We believe that CMS' failure to acknowledge or address the concerns and recommendations already raised by commenters is inconsistent with the statutory requirement that, in making budget neutrality adjustments, the agency must "consult with the Medicare Payment Advisory Commission and organizations representing physicians."[2] While we are deeply disappointed that CMS has thus far failed to fulfill its statutory consultation obligation or honor its commitment to respond to the health care community's concerns in this regard, we urge the agency to closely collaborate with us moving forward to mitigate the proposed CF reduction.

We understand that CMS believes that the proposed payment rate reduction is mandated by Medicare's BN requirements — section 1848(c)(2)(B(ii) of the Social Security Act (the "BN provision"). The BN provision requires that relative value unit (RVU) valuation changes that exceed a $20 million threshold must be offset by payment reductions for other PFS services. Of the $10.2 billion in additional spending attributable to changes described in the 2021 Medicare PFS proposed rule, only an estimated $5.6 billion is attributable to E/M service changes adopted last year (CPT codes 99202-99215; 99XXX)). An additional $3.3 billion is attributable to the adoption of the new E/M Office Visit Add-on Code (HCPCS GPC1X) and the remainder to various other spending provisions in the proposed rule. Thus, the modification of E/M coding and valuation finalized last year (CPT 99202-99215; 99XXX) accounts for only slightly more than half of the proposed conversion factor reduction.

CMS has significant administrative discretion in administering the BN provision, and the Administration has the power to mitigate the impact of this provision utilizing funds outside of the PFS under the

[1] The 2021 proposed rule increases the utilization assumptions for GPC1X relative to the CY2020 final rule in a manner that increases the cost of implementing the new code by $800 million.
[2] Social Security Act, §1848(9c)(2)(B)(iii).

unique circumstances of the Public Health Emergency (PHE) that is currently in effect. In this context, we urge CMS to consider mitigating the impact of the BN provision by taking the following actions:

1. Exercise its PHE authority to eliminate or mitigate the impact of the proposed BN reduction. Physicians and other health care professionals continue to face unprecedented public health and economic challenges as the result of the continuing pandemic.[3] Additional reductions in practice revenues could create significant access problems during a continuing public health emergency. We urge the Administration to exercise its considerable discretion to waive the BN provision and eliminate or substantially decrease the proposed BN reduction. In this regard, we note that CMS has, on numerous occasions, waived Medicare statutory provisions based on the Public Health Emergency. See Attachment B.

   In addition, we note that the Administration has issued an Executive Order related to the allocation of emergency funds without explicit statutory authorization. To the extent that CMS believes that it does not have the requisite authority to waive application of the BN provision to provide relief for the nation's physicians and non-physician practitioners, we urge the Administration to utilize emergency and other fund sources otherwise available to it to redress the proposed Medicare PFS payment reduction.

2. Eliminate the new E/M add-on code (GPC1X). Last year, CMS finalized the adoption of an ill-defined and controversial E/M add-on code to reflect visit complexity inherent in certain office/outpatient visits. CMS finalized this code over the objections of numerous commenters and despite commenters' serious concerns about the potential impact of this new code on budget neutrality calculations. In fact, if this code were not implemented, the proposed BN reduction would be reduced by about one- third. Moreover, due to the lack of specificity in the code descriptor for this service, CMS' BN calculations assume that the code will be billed whenever any E/M or outpatient visit is performed by virtually any medical specialty. Evidently, the CMS actuaries project that the code could be billed even for the most straightforward follow-up visit for a cold. There can be no clearer evidence that the code descriptor is not sufficiently specific. Furthermore, this add-on code is arguably entirely unnecessary, given how the E/M codes were restructured and valued.

   Importantly, the premature adoption of GPC1X for payment purposes not only will create open-ended liability for the Medicare Trust Fund but also will increase aggregate beneficiary copayments. Adopting the code in its current form has the potential to increase Medicare

[3] The Medical Group Management Association estimates that 97 percent of practices have experienced a negative financial impact directly or indirectly related to COVID-19, with practices reporting a 55 percent decrease in revenue and a 60 percent decrease in patient volume since the beginning of the spread.[3] Another recent study found that the number of visits to ambulatory practices declined nearly 60 percent between February 1 to April 16 — with larger declines among surgical and procedural specialties.[3] And a recent survey of surgeons found that one-in-three private surgical practices stated that they are already at risk of closing permanently due to the financial strain of the COVID-19 crisis. Data also reflect that 38 percent of physical therapy owners/partners reported that revenue had decreased 76 to 100 percent in the early phases of the pandemic, with another 34 percent reporting declines of 51 to 75 percent.[3] See Medical Group Management Association, COVID-19 Financial Impact on Medical Practices, April 13, 2020, https://www.mgma.com/resources/government-programs/covid-19-financial-impact-on-medical-practices. American Physical Therapy Association, Impact of COVID-19 on the Physical Therapy Profession Report, June 2020. https://www.apta.org/contentassets/15ad5dc898a14d02b8257ab1cdb67f46/impact-of-covid-19-on-physical-therapy-profession.pdf; see also American Physical Therapy Association, Impact of COVID-19 on the Physical Therapy Profession Report, August 2020. https://www.apta.org/contentassets/15ad5dc898a14d02b8257ab1cdb67f46/impact-of-covid-19-on-physical-therapy-profession.pdf

payment for the most commonly performed E/M services. At the very least, we strongly urge CMS to refer this add-on code to the CPT and RUC processes for review and refinement rather than implementing it this year. If CMS is unwilling to delay implementation of the code, we request that it be implemented on a "no-pay" basis in 2021, so that reliable utilization data can be collected for use in future BN calculations.

3. Consider the negative impact of COVID-19 on 2021 E/M visit utilization projections to calculate the BN adjustment. The BN provision requires that CMS make such adjustments as may be necessary to ensure that Medicare expenditures for Part B services do not exceed the amount that would be paid absent RVU changes. As a result of the pandemic, physicians and non-physician practitioners throughout the country ceased providing non-essential medical and surgical services, as directed by federal and state governmental authorities. At this stage, while some areas are reopening and experiencing a surge in pent-up demand for medically necessary services, due to the continued impact of the pandemic, overall patient utilization of E/M visits remains suppressed. One recent study published by the Commonwealth Fund finds:

> The number of visits to ambulatory practices fell nearly 60 percent by early April before rebounding through mid-June. From then through the end of July, weekly visits plateaued at 10 percent below the pre-pandemic baseline. The cumulative number of lost visits since mid-March remains substantial and continues to grow.[4]

The same study indicates that the number of Medicare visits remains 8 percent below the March baseline. In calculating the BN adjustment, we urge CMS to take into account the impact of the pandemic on the utilization of E/M services, and, specifically, to assume a continued reduction of at least 8 percent in the utilization of these services in 2021. Utilizing updated E/M utilization projections that are more likely to accurately reflect the continued impact of COVID-19 has the potential to significantly reduce the impact of the BN adjustment.

Alternatively, we urge CMS to utilize a base period more recent to 2019 to calculate the BN adjustment. We understand that CMS has already conducted an internal analysis of Medicare fee-for-service claims from March 17 to June 13, which captures pandemic-related utilization changes. The use of this and other 2020 data as the base period to calculate the BN adjustment may have the potential to significantly reduce the BN adjustment and mitigate or eliminate a devastating reduction in Medicare PFS payments.

Likewise, we believe it likely that the mix of E/M services provided to Medicare beneficiaries has shifted as the result of the pandemic. In the May 8 COVID-19 interim final rule with comment period (85 FR 27604-27605), CMS finalized on an interim basis a policy under which both physicians and non-physician practitioners may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, if the billing practitioner does not also furnish a higher-level E/M service to the patient on the same day. CMS is soliciting comments on whether this policy should be made permanent. To the extent that E/M utilization has shifted towards using this code for new or established patients, there may be a reduction in the BN adjustment.

[4] The Commonwealth Fund, "The Impact of the COVID-19 Pandemic on Outpatient Visits: Changing Patterns of Care in the Newest COVID-19 Hot Spots August 13, 2020 https://www.commonwealthfund.org/publications/2020/aug/impact-covid-19-pandemic-outpatient-visits-changing-patterns-care-newest.

In short, we strongly urge CMS to exercise its considerable statutory discretion to either (a) reduce the overall projected utilization of E/M services by at least 8 percent to reflect the drop in visits resulting from the continuing pandemic or (b) utilize a base period that reflects the reduced utilization of physicians' services resulting from COVID-19. We also request that CMS consider any data suggesting that the pandemic has resulted in a shift toward less intensive E/M services. Such actions have the potential to significantly mitigate the BN adjustment and to avert catastrophic PFS payment reductions.

4. Review its BN calculations to ensure that it accurately reflects the E/M billing policies that will become effective in 2021. For example, in last year's Medicare PFS final rule, CMS finalized a policy under which CPT codes 99358–99359 will not be payable in association with office/outpatient E/M visits beginning in CY 2021. Yet, the "CY 2019 Utilization Data Crosswalk to CY 2021" published in conjunction with the proposed rule includes 214,065 "undiscounted claims" for these services, suggesting that the proposed rule's BN calculation does not reflect this policy decision. We urge CMS to examine its BN calculations to ensure that any services that will not be billable in 2021 are not included in the calculation.

5. Utilize previous over-estimated spending to reduce the BN adjustment. Under the previous administration, CMS based the 2013 budget neutrality offset for Transitional Care Management on a significantly greater estimate of initial utilization of the service than actually occurred. At that time, CMS estimated there would be 5.6 million claims for TCM when actual utilization was just under 300,000 the first year and was still less than one million after 3 years of implementation. For 2013, the Obama Administration reduced Medicare physician fee schedule spending by more than $700 million based on its overestimate of TCM utilization. Given the statutory authority for budget neutrality adjustments to be made "to the extent the Secretary determines to be necessary," the statute allows CMS to account for past overestimates of spending when applying budget neutrality. **Accordingly, CMS could lessen the impact of the budget neutrality adjustment for the office visit increases in 2021 by restoring the over-estimated budget neutrality adjustment from the first few years of TCM.**

It is counter-intuitive to put forth drastic reductions to reimbursement at a time when both Congress and HHS are focused on engaging patients, increasing the delivery of integrated, team-based care, expanding chronic disease management, and reducing hospital admission/readmission rates for beneficiaries residing in the community as well as those in long-term nursing facilities. CMS must recognize how the reimbursement reductions for our providers fail to align with CMS' efforts to drive better patient access to care and management.

We appreciate the opportunity to comment on the proposed rule and look forward to continuing discussions with you regarding the critical issues raised by CMS' proposed budget neutrality adjustment.

Sincerely,

Academy of Nutrition and Dietetics
Alliance for Physical Therapy Quality and Innovation
American Academy of Audiology
American Academy of Dermatology Association
American Academy of Facial Plastic and Reconstructive Surgery

American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Oral and Maxillofacial Surgeons
American Association of Orthopaedic Surgeons
American Chiropractic Association
American College of Emergency Physicians
American College of Mohs Surgery
American College of Obstetricians and Gynecologists
American College of Osteopathic Surgeons
American College of Radiology
American College of Surgeons
American Health Care Association
American Occupational Therapy Association
American Physical Therapy Association
American Psychological Association
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Colon and Rectal Surgeons
American Society of Hand Therapists
American Society of Neuroradiology
American Society of Plastic Surgery
American Society for Radiation Oncology
American Society of Retina Specialists
American Society of Transplant Surgeons
American Speech-Language-Hearing Association
Association of Freestanding Radiation Oncology Centers
Association of Pathology Chairs
Association for Quality Imaging
CardioVascular Coalition
Clinical Social Work Association
College of American Pathologists
Congress of Neurological Surgeons
Dialysis Vascular Coalition
National Association of Rehabilitation Providers & Agencies
National Association of Social Workers
National Association for the Support of Long Term Care
National Center for Assisted Living
Private Practice Section of the American Physical Therapy Association
Select Medical
Society for Cardiovascular Angiography and Interventions
Society of Interventional Radiology
Society of Thoracic Surgeons

cc:
The Honorable Chuck Grassley
The Honorable Ron Wyden
The Honorable Richard Neal
The Honorable Kevin Brady

Attachment A

CMS Must Act to Halt Medicare Payment Cuts and Avoid Further Damage to the U.S. Health Care System

On August 3, 2020, the Centers for Medicare & Medicaid Services (CMS) issued its long-awaited 2021 Medicare Physician Fee Schedule (PFS) proposed rule. Physicians and nonphysician health care professionals across the United States are now bracing for harmful payment cuts that could jeopardize patient access to medically necessary services. The reductions are primarily driven by new Medicare payment policies for office and outpatient visits that CMS will implement on January 1, 2021. Drastic cuts caused by changes to these visit codes — also known as evaluation and management (E/M) codes — will further strain a health care system that is already stressed by the COVID-19 pandemic. Furthermore, primary care providers will have fewer choices when referring patients to specialists if health care professionals must close or limit their practices as a result of these cuts.

To help fortify the health care delivery system and ensure the long-term recovery post-pandemic, CMS must take steps to prevent steep payment cuts in 2021.

BACKGROUND

In 2019, CMS finalized broad changes related to E/M services to reduce administrative burden, improve payment rates, and reflect current clinical practice. The health care community supported restructuring and revaluing the office-based E/M codes, which will increase payments for primary care and other office-based services. Unfortunately, by law, any changes to the PFS cannot increase or decrease expenditures by more than $20 million. To comply with this budget neutrality requirement, any increases must, therefore, be offset by corresponding decreases. CMS estimates that the 2021 policies will increase Medicare spending by $10.2 billion, necessitating steep cuts by reducing the Medicare conversion factor from $36.0896 to $32.2605, or a 10.6 percent decrease.

MEDICARE CUTS WILL HURT PATIENTS

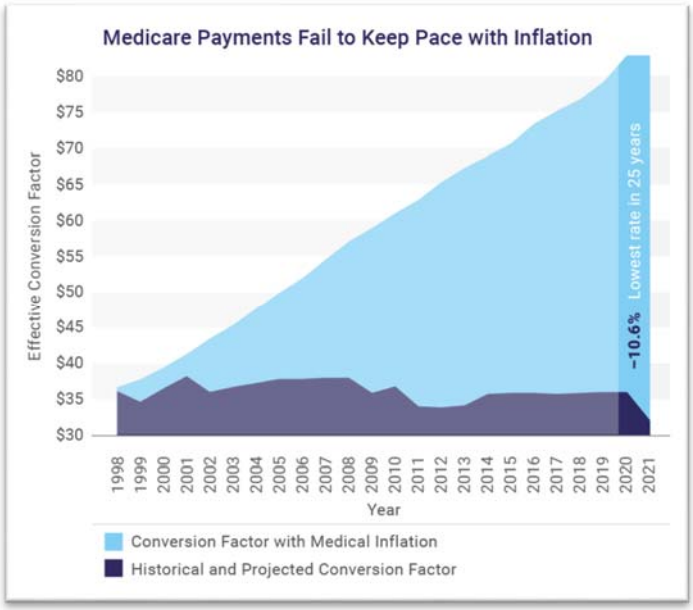
As the following table demonstrates, the impact of these cuts are devastating to health care professionals, their practices, and most importantly, their patients:

Specialty	Payment Change	Specialty	Payment Change
Nurse Anesthetist	-11%	Ophthalmology	-6%
Radiology	-11%	Portable X-Ray Supplier	-6%
Chiropractic	-10%	Radiation Oncology	-6%
Cardiac Surgery	-9%	Colon And Rectal Surgery	-5%
Interventional Radiology	-9%	Dietitian Nutritionist	-5%
Pathology	-9%	Gastroenterology	-5%
Physical/Occupational Therapy*	-9%	Independent Laboratory	-5%
Anesthesiology	-8%	Optometry	-5%
Critical Care	-8%	Oral/Maxillofacial Surgery	-5%
Nuclear Medicine	-8%	Orthopedic Surgery	-5%
Thoracic Surgery	-8%	Multispecialty Clinic	-4%
Audiologist	-7%	Infectious Disease	-4%
General Surgery	-7%	Hand Surgery	-3%

Neurosurgery	-7%	Physical Medicine	-3%
Plastic Surgery	-7%	Dermatology	-2%
Vascular Surgery	-7%	Podiatry	-1%
Emergency Medicine	-6%		

Data from Table 90: Proposed CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty
**This category includes Speech-Language Pathology.*

Compounding the problem is the fact that Medicare payments have failed to keep up with inflation since the inception of the PFS in 1992. This decrease in the 2021 conversion factor will be below the 1994 conversion factor of $32.9050 — which is worth approximately $58.02 today![5]



Even before the CMS cuts take effect, health care practices are already in distress due to the pandemic.

- According to a recent survey of surgeons,[6] one-in-three private surgical practices stated that they are already at risk of closing permanently due to the financial strain of the COVID-19 crisis. Many face difficult financial decisions and are responding by either cutting their pay, taking on debt, or laying off or furloughing employees.

- Additional surveys and claims analyses verify that COVID-19 reduced patient volume significantly and has resulted in substantial revenue losses for independent physician practices. Estimates of revenue losses range between 48% and 64% between March and May 2020.[7]

- While visit numbers have rebounded, they are still substantially lower than before the U.S. pandemic began. Over the past three months, forgone visits have created "cumulative deficits" in both patient treatment and practice revenue. The cumulative decline in visits from the start of the

[5] Using the U.S. Bureau of Labor Statistics inflation calculator, the conversion factor in 1994, $32.9050, is worth approximately $58.02 today. This means that the proposed CY 2021 cut of the conversion factor to $32.2605 is an even steeper cut when adjusted for inflation and is by far the lowest conversion factor since its inception in 1992. https://www.bls.gov/data/inflation_calculator.htm.

[6] Survey conducted by the independent public opinion research firm, Brunswick Insight. The online survey of 5,244 surgeons was conducted between May 11-20, 2020. https://www.surgicalcare.org/wp-content/uploads/2020/06/SCC_Member_Survey_Data_06172020_FINAL.pdf.

[7] Fair Health, Healthcare Professionals and the Impact of COVID-19; MGMA, COVID-19 Financial Impact on Medical Practices; AMGA, Surveys of Financial Impact of COVID-19; Primary Care Collaborative, Primary Care & COVID-19 Surveys. http://ndpanalytics.squarespace.com/the-impact-of-covid-19-on-independent-physician-practices.

pandemic is greatest among specialties like ophthalmology (-47%), dermatology (-42%), surgery (-41%), cardiology (-40%), orthopaedic surgery -39%), and obstetrics and gynecology (-28%).[8]

- It is not just physician practices in distress. Data also reflect that 38% of physical therapy (PT) owners/partners reported that revenue had decreased 76% to 100% in the early phases of the pandemic, with another 34% reporting declines of 51% to 75%.[9] Sixty-four percent saw fewer patients via direct access visits, and 88% reported a drop-off in physician referrals.

COVID-19 AMPLIFIES THE NEED FOR ACTION TO PREVENT THE CUTS

Health care professionals across the spectrum are reeling from the effects of the COVID-19 emergency as they continue to serve patients during this global pandemic. Consider the following:

- **Anesthesiologists** have been on the front lines of providing anesthesia and critical care services to Medicare patients infected by COVID-19. This care frequently involves high-risk intubation and extubation services — services that produce the highly infectious aerosolized form of the COVID virus. The projected 2021 payment cuts, on top of already low Medicare payments rates, will further weaken the practices of physician anesthesiologists involved in caring for critically ill patients.

- **Audiologists** play a critical role in the assessment and treatment of hearing loss and balance disorders that include those induced by viruses. Recent studies have indicated that individuals with COVID-19, including those who are asymptomatic, may experience damage to hair cells in the inner ear that can impair hearing function. Although research in this area is emerging as this novel coronavirus continues to spread, there is a growing need for Medicare beneficiaries — one of our most at-risk populations for COVID-19 — to have access to care provided by audiologists, both for COVID-19 and non-COVID-19-related hearing and balance-related problems.

- Extracorporeal membrane oxygenation (ECMO) is the treatment of last resort when COVID-19 patients fail to recover with ventilator support. A **cardiothoracic surgeon** hooks the patient up to a machine that either/both breathes and pumps blood, giving the patient's body a chance to rest and recover under the supervision of cardiothoracic surgeons and other health professionals trained in this specialized treatment. Cardiothoracic surgeons treat patients affected by three of four leading causes of death in the United States: heart disease, cancer (lung and bronchus), and chronic lower respiratory disease. Medicare reimbursement cuts could hinder patient access to life-saving care for these diseases.

- **Certified registered nurse anesthetists** (CRNAs) comprise over 50 percent of the U.S. anesthesia workforce and are expert clinicians with highly specialized skills that they have been providing since the COVID-19 pandemic such as airway management, ventilator support, vascular volume

[8] The Impact of the COVID-19 Pandemic on Outpatient Visits: Practices Are Adapting to the New Normal. Commonwealth Fund (June 2020). https://www.commonwealthfund.org/publications/2020/jun/impact-covid-19-pandemic-outpatient-visits-practices-adapting-new-normal.

[9] Impact of COVID-19 on the Physical Therapy Profession Report: A Report from the American Physical Therapy Profession (June 2020). https://www.apta.org/contentassets/15ad5dc898a14d02b8257ab1cdb67f46/impact-of-covid-19-on-physical-therapy-profession.pdf

resuscitation, and advanced patient assessment. The truth remains that CRNAs who do not frequently bill for outpatient evaluation and management procedures will see a cut in Medicare payment and that these decreases could impact a typical CRNA's payment by up to 11 percent.

- Doctors of **chiropractic** (DCs) are primary-contact healthcare providers who deliver essential care, including the management of acute and urgent musculoskeletal conditions like neck and low back pain. DCs are educated and licensed to diagnose, treat and co-manage patients and they work in private practices, multi-disciplinary clinics and hospitals across the country. Throughout the COVID-19 pandemic, DCs have continued to treat patients who may otherwise seek emergency care, helping to lessen the strain on frontline providers.

- **Dermatology** practices that perform fewer office E/M services will be especially hit hard, including those practices that provide dermatologic surgical care and dermatopathology practices. Reductions for these practices will be between 6% and 8% in 2021 and are in addition to the negative financial impact of COVID-19 where nine in ten dermatologists have reported losing more than half their income due to the public health emergency, as well as the increased cost of operating in this environment that disproportionately impacts physician doing surgical procedures.

- Seniors with diet-related conditions, including diabetes and chronic kidney disease, are suffering from the worst COVID-19 outcomes, including higher rates of death. Medical nutrition therapy provided by registered **dietitian nutritionists** has been proven to help these patients control their blood sugar, blood pressure and weight, slow the progression of diabetes and kidney disease, lower medication use, and avoid unnecessary emergency room visits and hospitalizations.

- Emergency departments (ED) across the U.S. continue to bear the brunt of the COVID-19 pandemic — **emergency physicians** in COVID-19 hotspots have worked tirelessly, often without sufficient personal protective equipment needed to keep them safe, as their EDs are overwhelmed with patients in desperate need of lifesaving care. In other cases, patient volumes have decreased by more than 40 percent (and as much as 60 percent) as patients defer necessary emergency care or avoid the ED altogether due to concerns about contracting the coronavirus. Further exacerbating the financial burden, most emergency physicians have received little if any financial relief under the CARES Act Provider Relief Fund, which has mainly been distributed to hospitals and not directly to emergency physician groups (it is estimated that emergency physician practices have received only 7 to 15 percent of what they need to make up for lost revenues and increased expenses due to COVID-19).

- Throughout the pandemic, **facial plastic surgeons** have assumed — at considerable personal health risk, with some developing COVID-19 as a result — various roles in assisting other physicians and medical professionals on the front lines in triaging and treating patients impacted by the novel coronavirus. Most facial plastic surgeons — and their staffs — throughout the country are experiencing extreme financial hardships, as a result of shutting down their medical practices and suspending elective surgeries in a proactive effort to dramatically curb the transmission of the virus, safeguard PPE supplies, and promote the public safety and wellbeing of their communities. Additionally, facial plastic surgeons have developed and are implementing guidance on the resumption of elective facial plastic surgical procedures to maximize safety and reduce the risk of COVID-19 transmission as states and their medical practices re-open.

- **Gastroenterology** practices are slowly re-opening and treating more patients after many states and Medicare placed a moratorium on elective endoscopy procedures earlier this year. GI practices were forced to shut down, leading to delays in needed care, including serious delays in colon cancer detection. At a time when practices are safely resuming care, CMS has now proposed deep cuts to these very GI services. CMS must prevent these looming Medicare cuts.

- **Hand surgeons** across the country had the majority of their revenue deeply cut when their elective office patient flow and surgical cases were canceled to preserve personal protective equipment (PPE) and due to fear of spreading the virus to crucial medical personnel. While emergent hand patients were treated surgically, this resulted in exposure to undiagnosed COVID-19. The severe revenue loss resulted in furloughs and layoffs of office staff, causing access to care challenges for patients.

- The proposed changes would have a significant impact on the **hand and upper extremity therapy** profession and to Medicare beneficiaries' access to needed care. With projected increases in elective hand surgeries due to increasing number of older adults as well as a prevalence of metabolic related disorders, hand and upper extremity therapy is a critical service. Hand and upper extremity therapy has been shown to be both: effective in decreasing the need for surgical intervention with successful conservative management, as well as key for improved patient outcomes in cases managed operatively. Close coordination between hand surgeons and hand therapists enables patients to progress as rapidly as appropriate with the goal of earlier recovery and maximized return of function. Effective hand and upper extremity therapy reduces cumulative costs by limiting the duration of rehab, the patient's time off work, and possible need for future surgical interventions. Upper extremity injuries are the most expensive injury annually, with productivity costs totaling more than direct health-care costs. Patients demonstrate improved functional outcomes following hand therapy for the treatment of surgically and non-surgically managed conditions. Hand and upper extremity therapy addresses main predictors of disability including the ability to work, pain, and psychosocial impact of injury.

- In many hospitals, **interventional radiology** (IR) was one of the few services that has remained open throughout the pandemic, providing emergency care to COVID-19 patients. IR services have included dialysis catheters and other venous access; drainage procedures such as abscess and cholecystectomy; and lysis procedures for COVID-19 patients with massive embolism and deep vein thrombosis. Nevertheless, canceled elective cases, the need for PPE, increased risks of caring for patients with COVID-19, staff reassignments — including technicians, nurses and physician— and private practices unable open while maintaining staff and benefits, has resulted in lost revenue, significant burnout and stress.

- **Neurosurgeons** are stepping up to lend their expertise on the frontlines of the COVID-19 pandemic, as well as continuing to take care of critically ill patients who suffer from painful and life-threatening neurologic conditions such as traumatic brain injury, brain tumors, debilitating, degenerative spine disorders, and stroke. Without timely neurosurgical care, patients can face permanent neurologic damage or death.

- Many **obstetrician-gynecologists** exclusively provide gynecologic services and were required to cancel all non-urgent procedures and office visits in the spring, reducing their practice revenues to almost nothing. For those ob-gyns that provide obstetric and gynecologic services, gynecologic services are essential to maintaining financial solvency due to inadequate reimbursement rates for obstetric care. The forthcoming cuts to gynecologic surgery — which average 7.4% — will be detrimental to ob-gyns who are already facing financial hardships and will put the future of private practice in jeopardy.

- **Occupational therapy** (OT) practitioners are working with patients across health care settings to promote recovery from the functional effects of COVID-19. These effects include COVID-19-related cognitive impairments, neuromuscular damage, fatigue, and psycho-social challenges — all of which interfere with one's ability to participate safely in necessary and meaningful day-to-day activities. OT services are crucial to achieving optimal function and long-term rehabilitation/recovery for people with COVID-19.

- **Ophthalmology** lost more patient volume due to the COVID-19 pandemic than any other medical specialty. Many practices were forced to furlough or lay off staff. Despite the challenges, ophthalmologists continue to treat patients with chronic conditions, such as glaucoma and macular degeneration, in addition to eye emergencies, retinal tears and detachments, eye strokes, eye infections, trauma, and cancer that can cause scarring, permanent damage or complete vision loss. Ophthalmologists are struggling to return to "normal" — working to rehire staff, if they're still available, managing a backlog of delayed care and instituting costly new safety procedures to protect their patients and staff from the virus. The proposed 6 percent Medicare pay cut for 2021 also doesn't tell the whole story. Cataract surgery faces a 9% reduction after experiencing a 15% reduction in 2020. Retina and glaucoma procedures are also facing 9% to 10% reductions in 2021. Ophthalmology practices — especially small private practices — that are still struggling to recover from the COVID-19 pandemic will be devastated by these substantial payment cuts. Our already weakened health care system can't take anymore.

- **Orthopaedic surgery** practices have stepped up throughout the COVID-19 pandemic, abstaining from elective surgery to preserve life-saving PPE. Practices are now working against significant patient backlogs and are struggling to catch-up working with limits on operating room time and, in many cases, with a reduced staff. Orthopaedic surgeons are now facing Medicare payment cuts for total hip arthroplasty and total knee arthroplasty, on top of the proposed E/M cuts. This double reduction will result in Medicare payment cuts of up to 10% for these procedures, and if not quickly addressed by CMS, access to musculoskeletal care will be significantly threatened.

- **Pathologists** are integrally involved in direct mitigation of the COVID-19 crisis, including testing for accurate and timely diagnosis and potential cures. These cuts will have a significant impact on pathology at a time when patients and their treating physicians are relying on the expertise of pathologists. There are still challenges in increasing COVID testing and supply chain management. When you combined those critical issues with 9% cuts pathologists are facing next year, it will have a devastating impact on practices, and ultimately patient care.

- **Physiatrists**, specialists in **physical medicine** and **rehabilitation** treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles and

tendons. Physiatrists utilize cutting edge as well as time tested treatments to maximize function and quality of life. In response to COVID-19, physiatrists have played a unique and critical role, ensuring that patients experiencing severe complications from the virus are able to restore function and optimal health. Congruently, many physiatry practices are suffering financially during the pandemic. The proposed cuts would create barriers for Medicare beneficiaries needing to access physical medicine and rehabilitation care, including beneficiaries who have lost significant function due to the virus, by making it harder for practices to accept Medicare or even stay open.

- Once patients recover from COVID-19 symptoms, their journey is not over. Hospitalization and bed rest can lead to complications of the musculoskeletal system, including strength loss, atrophy and contracture, as well as be devastating to the cardiopulmonary system. **Physical therapists** (PT) and physical therapist assistants are providing rehabilitation to patients with muscle weakness and limitations in strength and function due to their ICU stay, as well as cardiac rehabilitation, to help patients recover.

- Although the pandemic has changed the way many board certified **plastic surgeons** practice, it has also provided a call to action that the specialty, as it has during so many crises, continues to answer. Beginning in March plastic surgeons worked directly with the White House COVID-19 Task Force, Federal Emergency Management Agency and the National Safety Council. Rallying members and using connections to industry and suppliers, plastic surgeons donated five million NIOSH certified N95 masks; one million FDA certified N95 masks; and 20,000 surgical masks. They also created a national clearinghouse where plastic surgeons offered to donate ventilators to hospitals in short supply. From donating desperately needed medical and personal protective equipment to coordinating hospital logistics to handle surges of patients to finding new ways to consult and follow-up with patients, plastic surgeons continue to go above and beyond to help each other, their communities and countless others through this unique moment in history. Plastic surgeons also developed a broad range of resources to provide guidance to ensure patients continue to receive the reconstructive care they need.

- **Psychologists** are Medicare's primary providers of mental and behavioral health services, diagnostic services, and psychological and neuropsychological tests and assessments. The COVID-19 public health emergency is taking a heavy toll on the mental health of Medicare beneficiaries and all Americans. According to June data from the Kaiser Family Foundation, more than one-third of U.S. adults reported symptoms of anxiety or depressive disorder, more than three times the number in 2019. Based on the consequences of previous epidemics, experts predict that the mental health impacts from COVID-19 will continue well after the end of the public health emergency.

- Medicare's proposed 6% E/M cut for **radiation oncology** rubs salt in the open wound for radiation therapy clinics, as most struggle with revenue declines of 20-30% or more due to COVID-19. The National Cancer Institute predicts that COVID-19 will lead more patients to present with later-stage cancer, requiring radiation oncology physicians to treat more challenging cases with fewer resources unless CMS stops the E/M cuts.

- Particularly in areas where COVID-19 testing kits are not widely available, medical imaging is used to help confirm COVID-19 findings, gauge the extent of illness and determine effective treatment. As **radiology** practices followed WHO and CDC guidance to postpone non-urgent

care, and Americans worried about infection risk, cancer screenings — including mammograms — and other oncologic imaging plummeted. Major cancer diagnoses are down 46 percent. Seventy percent of radiology practices had to take out small business loans or federal relief options to survive the pandemic's financial toll. Drastic imaging cuts now may drive practices out of business, restrict access to care and cause a spike in adverse health outcomes — including deaths.

- **Social Workers** with clinical licensure (LCSWs) provide assessment, diagnostic and psychotherapy services for children, adolescents, adults, couples, families and groups. As the largest group of mental health professionals in the country (over 250,000 practitioners), LCSWs work in a broad range of settings. LCSWs also assess and provide resources for the Social Determinants of Health (SDOH), e.g., housing, income, health care, nutrition, etc. The exponential increase in panic and hopelessness experienced by Medicare beneficiaries, in particular, is leading to a higher rate of suicidality, especially in people of color, according to the Centers for Disease Control and Prevention. It should be noted that LCSWs are currently being reimbursed at a rate that is 25% less than other Medicare mental health providers for the very same services. Thus, the additional 6% cut to reimbursement will make it difficult for CSWs to continue providing services to Medicare beneficiaries.

- **Speech-language pathologists** (SLPs) provide critical speech, swallowing, and cognitive care to individuals with COVID-19 — especially those who currently are, or have been, intubated as a result of the need for mechanical ventilation. SLPs help facilitate communication between these patients and their other providers through a variety of ways to improve patient care and treatment outcomes, and provide essential speech and swallowing therapy post-intubation. Some patients who have been intubated or have received low oxygen to the brain during the COVID-19 episode may also have persistent cognitive issues (e.g., memory impairments). As part of the patient's healthcare team, SLPs can help the individual lead a more independent life to reduce adverse outcomes such as rehospitalizations and reduce health care costs.

- Due to age and multiple comorbid conditions, residents of **skilled nursing** and **long term care facilities**, such as assisted living, are the most vulnerable population impacted by COVID-19 — with incidence and mortality rates much higher than all other demographics. While more than 80% of this population that is infected successfully survives COVID-19, these patients frequently experience significant loss of weight, strength, mobility, and ability to perform activities of daily living, and enjoy life at a level possible prior to the pandemic. These individuals will often need various and sometimes extensive and long-term therapy to restore their abilities to eat, move about, and perform daily activities as independently as possible. Reduced access to PT, OT, and SLP rehabilitation services resulting from the proposed draconian cuts to PFS payments would result in a lower quality of life for nursing facility residents and higher and costly rates of institutionalization of assisted and senior living residents who are unable to restore functional losses experienced during the acute phase of their COVID-19 illness.

- **Surgeons** have continued to operate on patients in need of critically important procedures during COVID-19 that saved lives and improved patients' quality of life. Many surgeons have served on the frontlines of the pandemic, helping the sickest patients fight COVID-19 and treating non-surgical patients who have contracted the disease.

BOTTOM-LINE

The health care community appreciates CMS' efforts to restructure and revalue the office-based E/M codes. However, we are deeply concerned that adhering to existing budget neutrality requirements for implementing the new policy will do lasting damage to the health care system — particularly in light of the COVID-19 crisis. **As such, CMS should take the necessary steps to prevent steep cuts associated with the finalized E/M code policies slated for implementation on January 1, 2021.**

Attachment B

Topic	Description of Policy	Description of Waiver	Waiver Authority
Examples of Provisions Waived without Explicit Waiver Authority			
Accelerated and Advanced Payment Programs	Section 1815(e)(3) of the Act provides authority to make accelerated payments to inpatient prospective payment system (IPPS) hospitals. Regulatory and manual provisions dictate loan and repayment terms. 42 CFR §421.214 provides advanced payment to suppliers when a Medicare contractor transition interrupts payment. Implementing regulations for the advanced program do not cite CMS' statutory authority. A supplier does not include a "provider of services." Section 1861(u) of the Act defines a "provider of services" to include a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA) and hospice. Hospitals would include IPPS hospitals, LTCHs, inpatient rehabilitation facilities and inpatient psychiatric facilities (IPF), cancer hospitals and children's hospitals.	Section 3719 of the CARES Act expanded the accelerated program to children's hospitals, cancer hospitals and CAHs. Under 42 CFR §421.214, CMS is providing advanced payment to suppliers and providers of services other than those explicitly addressed by statute through the accelerated program. CMS has been inconsistent in whether the advanced or accelerated program applies to LTCHs, IRFs and IPFs. The accelerated payment program has more generous loan and repayment terms than the advanced program.	The statutory authority for the accelerated program is limited to IPPS hospitals, children's hospitals, cancer hospitals and CAHs. CMS does not have explicit statutory authority to expand the program to IRFs, IPFs and LTCHs, although it has indicated through informal communications that these types of hospitals are subject to the accelerated program. The regulatory authority for the advanced program is limited to Part B suppliers that would not include IRFs, IPFs, SNFs, CORFs, HHAs and hospices even though CMS indicates in its official communications that these provider types are subject to the advance program.

Topic	Description of Policy	Description of Waiver	Waiver Authority
LTCHs	LTCHs are required to have an ALOS of 25 days or more.	CMS has advised LTCHs not to count admissions or discharges in order to meet the demands of the emergency towards the 25-day average length of stay requirement.	Section 1861(ccc) of the Act requires the LTCH to have an ALOS of 25 days. There is no provision to waive this requirement. There is a parenthetical in the statute "as determined by the Secretary" after "average inpatient length of stay." This provision gives the Secretary authority to calculate the ALOS but not change the 25 days.
Sole Community Hospitals (SCH)	Under section 1886(d)(5)(D)(iii) of the Act, an SCH must be more than a specified distance from another hospital depending on the topography of where the SCH is located.	For a hospital classified as an SCH prior to the PHE, CMS is allowing a hospital to continue to be paid as an SCH even if it no longer meets these statutory requirements.	The SCH provisions are conditions of payment. There are no explicit statutory provisions to waive the SCH distance requirements.
Medicare Dependent Hospitals (MDH)	Under section 1886(d)(5)(G)(iv), an MDH must have fewer than 100 beds and Medicare utilization of 60 percent or more.	For a hospital classified as an MDH prior to the PHE, CMS is allowing the hospital to continue to be paid as an MDH even if it no longer meets these statutory criteria.	The MDH provisions are conditions of payment. There are no explicit statutory provisions to waive the 100-bed limit and Medicare utilization requirements.
Inpatient Rehabilitation Facilities (IRF)	To receive payment as an IRF, 60 percent of the IRF's patients must have a specific diagnosis requiring rehabilitation (the 60 percent rule). Also, IRFs are required to provide at least 3 hours of intensive therapy per day or 15 hours per week (the 3-hour rule).	CMS is waiving both the 60 percent rule and the 3-hour rule.	Both of these requirements are regulatory. Through an IFC published on April 6, 2020, CMS indicated that IRFs are not required to meet the 3-hour rule during the PHE in specific circumstances. Section 3711(a) of the CARES Act later waived the 3-hour rule.

Topic	Description of Policy	Description of Waiver	Waiver Authority
			CMS did not undertake rulemaking to change the 60 percent rule, and there is no explicit statutory authority to waive it.