July 1, 2020

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), the largest medical specialty organization and the second largest physician group in the United States, thank you for the opportunity to provide comments on the Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program interim final rule (IFR). The College enthusiastically welcomes the actions taken by the Centers for Medicare and Medicaid Services (CMS) to date, which have extended regulatory flexibilities for physicians on the front lines of the COVID-19 pandemic who are working to care for patients. These changes have allowed internists to focus on delivering direct patient care while spending less time on administratively burdensome tasks.

We hope that our comments and recommendations below will prove beneficial to CMS as the Agency continues to work on responding to the COVID-19 pandemic in the United States. The College appreciates this opportunity to offer our feedback, and we look forward to continuing to work with the Agency to implement policies that promote the health and safety of patients during this public health emergency (PHE). The discussion below provides more detailed comments on the changes listed in the Agency's IFR.

Payment for Audio-Only Telephone Evaluation and Management Services

As the College has noted in previous communications, ACP wholeheartedly supports the Agency's actions to provide additional flexibilities for patients and their doctors by providing payment for telephone E/M services — and through this IFR, to provide payment parity between telehealth E/M codes 99201-99215 and telephone E/M codes 99441-99443 by cross-walking telephone E/M codes to E/M codes 99212-99214 and adding these codes to the Medicare telehealth list. These changes in payment policy address some of the biggest issues facing physicians as they struggle to make up for lost revenue and provide appropriate care to patients. ACP values the opportunity to communicate with CMS about these issues, and we are very appreciative of the Agency's receptiveness to our concerns by adopting these recommended changes.

The College recommends that CMS maintain pay parity between telephone E/M claims and in-person

E/M visits and between all telehealth and in-person visits even after the PHE is lifted. This extension should last at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these visits. First, emerging evidence suggests that patient visits to ambulatory practices have declined significantly and despite a rebound, visits remain 30% lower than they were pre-pandemic. Given the uncertainty around the timeline for a COVID-19 vaccine or treatment, many expect that the virus will continue to spread well into 2021. Therefore, as the need to contain the virus and maintain appropriate social distancing protocols continues into next year, it is unlikely that in-person visits to practices will return to pre-pandemic levels as patients remain uncomfortable with making these in-person visits and physicians schedule fewer patients to be seen in the office.

Second, patients have become accustomed to and appreciative of telehealth/telephone visits, and many appreciate the flexibility these visits provide. The transition from in-person visits to the greater use of telehealth and telephone visits during this PHE has provided patients a safe option of receiving equivalent or nearly equivalent care to what they otherwise would receive in an in-person setting in an effort to control the spread of COVID-19. Third, physicians will also have to adjust their workflows and practices to allow for appropriate social distancing protocols and prevent patient infection. This again will mean that, in many cases, practices will not be able to maintain economic viability without maintaining payment for these remote services.

Finally, internists are skillfully adapting to gathering necessary information via telehealth or the telephone that they would have gathered during an in-person visit. The use of telehealth has allowed physicians to visit patients virtually in their homes, allowing in some cases for unexpected improvements in care, as the clinician may better be able to identify the impact of social determinants on a patient's health. It is imperative that physicians and payers have an opportunity to evaluate the impact of these changes and adapt before moving forward. Moreover, it is essential that policies align in such a manner as to allow physician practices to gradually resume healthcare activities that have been modified, delayed, or stopped altogether. As the College laid out in recent policy guidance, ACP strongly encourages CMS to chart a way forward that allows healthcare services to be resumed in a phased and prioritized way, based on the best available evidence, in a manner that mitigates risk (slows and reduces the spread of COVID-19, and associated deaths and other harm to patients), and rapidly expands health system capacity to diagnose, test, treat, conduct contact tracing (with privacy protections), and conduct other essential public health functions.

ACP has long believed that healthcare innovation is important for the sake of patients and their health. Hence, given the breadth of systematic changes and the need for physicians and payers alike to fully evaluate and understand their impact, we again urge the Agency to allow these changes to remain in place at least through the end of 2021 to allow all stakeholders to determine what innovation will look like for the future of healthcare. We look forward to working with CMS to address these discrepancies.

To build on these positive changes, ACP continues to recommend that CMS establish clear guidelines around billing for telephone E/M claims. The Agency did note that the office/outpatient E/M level of selection for telehealth E/M services can be based on medical decision-making (MDM) or time, with time defined as all of the time associated with the E/M visit on the day of the encounter. **We encourage CMS to allow clinicians to use the same aforementioned guidelines when billing telephone E/M claims. It is important that clinicians have similar rules and guidelines to minimize administrative complexity and maximize their time focused on delivering patient care.**

Finally, we strongly encourage CMS to remove the requirement that telephone E/M visits not originate from a related in-person E/M visit within the past 7 days or lead to an E/M visit/procedure within the next 24 hours. It is critically important that CMS work to remove barriers that may prevent patients from accessing the care they need at the time they need it. It is possible that patients will need follow-up visits to prevent the exacerbation of a condition or to monitor symptom presentation to determine the need for a COVID-19 test. For example, if a patient had an in-person visit in the last 7 days where the physician determined that a follow-up visit was necessary but could be done remotely, this language would not allow a remote visit to be billable. Additionally, this language does not allow an in-person follow-up visit to be billed following a remote visit if that remote visit occurred within the previous 24 hours. We encourage CMS to ensure that the language in this code descriptor does not inadvertently subject high-risk groups to COVID-19 infection due to the inability of practices to use in-person and telephone visits in concert with each other.

Flexibilities in Direct Supervision by Physicians at Teaching Hospitals

In the IFR published by CMS to combat the COVID-19 PHE, the Agency noted that in instances where direct supervision is required by physicians and at teaching hospitals, CMS will allow supervision to be provided using real-time interactive audio and video technology. Additionally, this IFR from the Agency notes that CMS will now allow teaching physicians to review services provided with the resident during or immediately after the visit. Physicians may conduct these services remotely through virtual means via audio/video real-time communications technology. CMS has also outlined additional guidance that will allow Medicare to make payment to the teaching physician for additional services when furnished by a resident under the primary care exception. This will allow payments to be made for low to mid-level E/M services provided by a resident when the teaching physician is not present, provided that certain other requirements are met.

Finally, CMS notes that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making (MDM) or time. Time is defined as all of the time associated with the E/M on the day of the encounter. Additionally, the requirements regarding documentation of history and/or physical exam in the medical record do not apply under this exception. The College welcomes these changes by the Agency that will grant attending physicians and residents/fellows additional flexibilities that prioritizes patient safety and meets them where they are. These important steps promote efficient patient care and allows physicians and supervisees to work together unencumbered by social distancing restrictions. **We encourage CMS to maintain these modifications for a period of time after the PHE ends and until supervising physicians feel comfortable they are able to control the spread of infection rates. This extension should last at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further based on the experience and learnings of patients and physicians who are utilizing these supervision flexibilities. The College remains ready and willing to work with CMS on these changes to ensure that they work in harmony with the additional historic actions taken to date.**

Opioid Treatment Programs Flexibilities

The onset of the COVID-19 pandemic has increased concerns that it may worsen the opioid epidemic in the United States that has already taken thousands of lives. The American Society of Addiction Medicine (ASAM) has described several COVID-19 risks associated with substance use disorders that speak to these concerns. ASAM notes that the following mechanisms increases the probability of contracting COVID-19:

- Inhalation of drugs likely increases exposure to and generation of aerosolized respiratory fluids;
- Drugs that suppress respiratory drive may interact with adverse respiratory effects of COVID-19,

contributing to increased risk of severe illness as well as overdose;
- Alcohol and many illicit drugs have direct and indirect immunosuppressing effects, particularly when used heavily and chronically;
- Smoking any substance, including tobacco and vaping may increase vulnerability to coronavirus infection and developing COVID-19;
- Drugs that constrict blood flow may interact with hematological effects of coronavirus to increase risk of coagulopathies and/or ischemic disease;
- Communal living, incarceration, homelessness, and poor hygiene increase exposure to the coronavirus;
- People who have substance use disorders are driven by the disease to take risks that others might not. As a result, they may be less likely to maintain social distancing than others, and the novel coronavirus may be more likely to spread in this population; and
- Patients with substance use disorders, due to prejudice and stigma, are less likely to seek acute medical services for serious symptoms.

Treatment at an opioid treatment program (OTP) requires that patients receive most of their treatment services in person. Given the guidance by federal and state officials that individuals practice social distancing and avoid activities that may increase the probability of contracting COVID-19, it is imperative that regulatory agencies and insurance programs provide flexibilities for patients suffering from addiction to continue treatment in a safe, effective manner. **ACP is pleased to see that CMS has extended flexibility to OTPs to allow these programs to offer periodic assessments, therapy, and counseling services via telehealth or audio-only capabilities when video is not available. These changes will provide additional options for patients and their care teams while working to minimize their risks of infection from COVID-19. We encourage CMS to work with ASAM and the larger medical community to determine whether these flexibilities should be extended beyond the current PHE.**

Revised Policies for Remote Patient Monitoring Services

In this IFR, CMS announced that for the duration of the PHE, the Agency will allow remote patient monitoring (RPM) services to be reported for periods of less than 16 days but not less than two days, as long as the other requirements for billing the code are met. CMS notes that it is not currently prepared to alter the payment for RPM because it believes "the overall resource costs for long-term monitoring for chronic conditions assumed under the current valuation would appropriately reflect those for short-term monitoring for acute conditions in the context of COVID-19 disease and exposure risks." Payment for these codes (CPT codes 99454, 99453, 99091, 99457, and 99458) for services less than 16 days but longer than two days is limited to patients who have a suspected or confirmed diagnosis of COVID-19. CMS previously finalized policy that allows RPM to be used for both new and established patients and allows consent to receive RPM services to be obtained once annually, including at the time services are furnished for the duration of the PHE for the COVID-19 pandemic. CMS has also established through previous rulemaking that RPM codes can be used for both acute and chronic conditions.

The College applauds the Agency's decision to expand access to RPM codes by allowing physicians to bill them for both new and established patients during the PHE. These changes expands access to these services at this important time when patients and their care teams need additional resources to meet the current challenges. These changes will help to relieve physician burden and allow physicians more time to treat the more complex patient issues that require more than remote monitoring. **We strongly encourage CMS to maintain these modifications at least through the end of 2021, or until such a time when effective vaccines and treatments are widely available, with an option to extend it even further, or consider making permanent, based on the experience and learnings of patients and physicians who are utilizing these services.**

Facility Fee Payment for Provider-based Departments

Typically, if a provider-based department (PBD) located on a campus hospital (and therefore was paid the hospital Outpatient Prospective Payment System (OPPS) rate) relocates to be off-campus, it would have to bill the reduced rate. However, it was recognized that it would be extremely difficult to sustain the PBD at the lower rates if it relocates due to COVID-19. Therefore, in order to provide greater flexibility to hospitals so that they can rapidly deploy temporary expansion sites and thus improve patient access to care, CMS has temporarily adopted an expanded version of the extraordinary circumstances relocation policy during the COVID-19 PHE. This means that during this time on-campus PBDs can relocate off-campus and still bill at the OPPS rate — but to do so, their affiliated hospital must align their PBD relocations with the state's emergency preparedness or pandemic plan to ensure continuity with state efforts. The College does not support provider-based billing for care delivered in an outpatient, hospital-system owned practice when that care is not dependent on the hospital facility and its associated technologies. Rather, in line with the College's high value care initiative, ACP supports delivery of care in the most efficient setting while maintaining quality of care. As we have stated previously, the expansion of telephone and telehealth services have allowed patients to connect with their care teams while protecting their health and that of others. If patients are receiving care from a PBD from their home, they are using the hospital's technology based platforms and other associated technologies to support the care provided. Therefore, ACP supports CMS' temporary policy to allow hospitals to bill a facility fee when the patient is an established patient of a provider-based outpatient department and receives care via telehealth services at their home. These policies allow for the ability to contain infection rates while still providing necessary care to established patients through established PBDs. **Risk-based assessments are needed before these types of facilities are expected to shift back to regular face-to-face visits. Therefore, ACP recommends this policy remain in place for an extended period of time after the designation of the PHE, possibly through the end of 2021, or until such a time when effective vaccines and treatments are widely available.**

Time Used for Level Selection for Office/Outpatient Evaluation and Management Services Furnished via Medicare Telehealth

CMS clarified in their second IFR that typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor. This marks a change from the last IFR where the Agency ruled that when time is used for the purposes of code selection, the typical times would be those that were available in a public use file. This change is in conjunction with changes finalized under the previous IFR that permitted physicians to use medical decision-making (MDM) or time when billing for E/M telehealth visits, maintained the current definition of MDM for the duration of the PHE, defined time as all of the time associated with the E/M visit on the day of the encounter, and temporarily removed any requirements regarding documentation of history and/or physical exam in the medical record.

Similar to our previous comments, ACP strongly supports this clarification about time when billing for telehealth E/M services. This change permits congruity between level of selection requirements for face-to-face E/M services and telehealth E/M services, allowing for further burden reduction on the part of physicians and increasing access to services for patients. We continue to believe these policies will improve patients' access to care by enabling doctors to spend more time with their patients and less time on unnecessary documentation. The College welcomes these additional changes to telehealth E/M documentation requirements and believes that they will be essential to enhancing care delivery by improving care outcomes, increasing longevity, lowering costs, and reducing preventable hospital and emergency room admissions while allowing patients to maintain their safety. We look forward to working with CMS to ensure that these finalized policies work in sync with E/M changes scheduled to go into effect in 2021.

Nursing Facilities

New regulations from CMS note that, effective immediately, CMS will require facilities to electronically report information about COVID-19 in a standardized format specified by the Secretary. The report should include information on: suspected and confirmed COVID-19 infections among residents and staff, including residents previously treated for COVID-19; total deaths and COVID-19-associated deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID-19 testing while the resident is in the facility; staffing shortages; and other information specified by the Secretary. The IRF notes that facilities will be required to provide an update at least weekly to the CDC, and the information will be reported publicly. Additionally, CMS states in the IFR that facilities must inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff by certain timelines. **Given the disproportionate share of COVID-19 cases, deaths, and hospitalizations experienced by residents of skilled nursing facilities, ACP welcomes efforts by CMS to provide transparency about the status of these facilities. It is critically important that residents, their families, and facility staff have access to this information to plan and properly take care of their own health and safeguard the health of those in their care. We encourage CMS to add COVID-19-associated hospitalizations to the list of reportable metrics so that all appropriate metrics are being reported to ensure transparency.**

Adding Services to the Medicare Telehealth List

Given the nature of the COVID-19 pandemic and in an effort to update more readily the list of available telehealth services, CMS notes in this IFR that it will use a sub-regulatory process to refine the services on the telehealth list during the PHE. The Agency has not yet defined what that sub-regulatory process will be. **ACP encourages CMS to define expeditiously this sub-regulatory process to ensure that patients, physicians, and medical societies have the necessary information to work with the Agency to properly develop, define, and submit information to aid CMS in any subsequent additions to the Medicare telehealth list.**

<u>Medicare Shared Savings Program (MSSP)</u>

Participation Flexibilities

CMS notes in the IFR that Accountable Care Organizations (ACOs) whose current agreement periods expire at the end of 2020 will have the option to extend their existing agreement period by one year. ACOs in the BASIC track may elect to maintain their current level of risk in 2021. CMS will provide additional guidance on the process and timeline for making both elections. ACOs that make no election will automatically advance to the next level of the glide path in 2021. ACOs that do elect to remain at their current risk level in 2021 will revert to the level they would have participated in for Performance Year (PY) 2022, skipping a level. **ACP strongly supports these important flexibilities, which as CMS notes in the rule will provide assurance and consistency to ACOs at this tumultuous time.**

Clarification to the Extreme and Uncontrollable Circumstances Hardship Exception

CMS clarified in the IFR that the timeframe for mitigating shared losses under the extreme and uncontrollable circumstances exception will start in January 2020 (as opposed to March 2020) and continue through the end of the PHE. **ACP appreciates this important clarification. We also note that practices will not recover from COVID-19 overnight; the effects of crisis will be long lasting. Accordingly, CMS should be prepared to extend important flexibilities like this beyond when the immediate PHE has concluded, through at least PY 2020, as well as monitoring the long-term impact on patient attribution, performance measure benchmarks, and target pricing and historical financial benchmarks.**

Adjustments to Benchmarks and Savings/Losses Calculations

The IFR notes that CMS will exclude all Parts A and B payments for COVID-19 episodes of care triggered by an inpatient admission at an acute care hospital or other eligible healthcare facility, including temporary expansion site. Specifically, services with ICD-10 code B97.29 (other coronavirus as the cause of diseases classified elsewhere) and discharge dates Jan. 27 – March 31, 2020 and services with ICD-10 code U07.1 (COVID-19) and discharge dates starting April 1 through the duration of the COVID-19 PHE are eligible. Episodes start the month of admission and continue through the month following discharge. This change will affect Parts A and B expenditures "for all purposes" including shared savings/losses calculations, high/low revenue ACO distinctions, loss sharing limits, regional and national growth rate adjustments and caps, historical benchmarks, and risk adjustment. Recouped or accelerated payments and lump sum payments made through the CARES Act Provider Relief Fund (PRF) will not affect MSSP expenditure calculations.

ACP appreciates CMS adjusting MSSP benchmarks to account for the impact of COVID-19 on expenditures and clarifying that lump sum payments made through the CARES Act PRF will not adversely impact ACO expenditures. These critical changes will help to protect ACOs from circumstances out of their control at a time of immense financial risk and will provide them with important protections to continue participating in the program. While ACP appreciates CMS' point that hospital inpatient costs comprise a majority of overall costs for the treatment of COVID-19, CMS acknowledges in the rule that at least 10% of COVID-19-related costs would not be captured by these inpatient triggered episodes, which still represents a potentially sizable deviation, particularly for non-hospital-based MSSP ACOs. **CMS should continue studying the impact of COVID-19-related outpatient codes and consider adding them to the list of services excluded from MSSP expenditures. ACP would also like to reiterate that the effects of the COVID-19 crisis will last well beyond the technical conclusion of the PHE. Because CMS is already restricting this expenditure adjustment to a very select group of codes inherently tied to treatment of COVID-19, we do not believe establishing an artificial cutoff point is necessary in this case.**

While this is an important start, the full impact of COVID-19 extends beyond the inpatient codes directly related to treating COVID-19 patients. COVID-19 has completely changed business as normal as ACOs divert all kinds of staff and infrastructure resources toward controlling and preventing the spread of infection, which means disrupting business as usual in myriad ways. **ACP strongly supported CMS' decision to cap actual prices at target prices for episodes of care that occur during the COVID-19 PHE for the Comprehensive Care for Joint Replacement Model (CJR). Similarly, ACP urges CMS to cap actual expenditures at expected expenditures for the MSSP and other benchmark-based population models, effectively holding participants harmless from financial losses for the 2020 performance year. At a minimum, CMS should allow ACOs to opt for lower shared savings rates in exchange for reduced downside risk. Circumstances have drastically changed since ACOs performed their original cost benefit calculations and signed their participation agreements in light of the COVID-19 PHE.**

CMS should also consider adjustments to Advanced APM bonuses to account for the lower-than-anticipated revenue resulting from the COVID-19 epidemic. ACOs and other APM Entities worked hard to meet rigorous financial risk, technology, and quality improvement requirements and should not be penalized due to an unforeseen drop in revenue and higher than anticipated costs for treating patients on the front lines of a public health crisis. One option would be to make a one-time exception and base 2021 bonuses on revenue from the 2019 performance year as opposed to the 2020 performance year. This would also allow CMS to make PY 2019 Advanced APM lump sum bonus payments sooner. CMS should similarly look to expedite 2019 MSSP shared savings payments and Advanced APM bonus payments for PY 2018. Practices need all the financial support possible to weather this storm.

Expansion of Codes Used in Beneficiary Assignment

For 2019 and subsequent PYs, services reported on an Federally Qualified Health Center/Rural Health Clinic claim will count as primary care services for purposes of assignment. For 2020 and any future years affected by the COVID-19 PHE, services that are furnished virtually but not considered Medicare telehealth for which payment has been authorized during the COVID-19 PHE will count as primary care services, including remote evaluation of patient video/images, virtual check-ins, e-visits, and telephone E&M visits. Initial nursing facility stays, nursing facility discharge management, and home visits for new and established patients will count towards patient assignment when furnished using telehealth beginning March 1, 2020 for the duration of the PHE.

ACP generally supports the adjustments to the definition of primary care services for purposes of patient assignment that reflect accommodations to the way these services are delivered in the midst of the COVID crisis. However, ACP advises CMS to monitor closely the impact of these policy adjustments on patient assignment, including any potential unintended consequences. We appreciate CMS acknowledging in the IFR that there will likely be longer lasting effects of the COVID-19 pandemic that may necessitate additional rulemaking and adjustments to the MSSP and other APM policies, including rebounding elective procedure costs in 2021 following potentially sustained reductions in 2020, which may affect patient attribution and ACO expenditures. In that vein, we also wanted to reiterate the importance of CMS extending important flexibilities like the ones included in this IFR for the MSSP for all APMs, particularly Advanced APMs. **ACP appreciates CMS' recently announced accommodations for several CMS Innovation Center models, but these do not go far enough. As outlined in our letter seeking long-term protections for clinicians engaged in the Quality Payment Program, particularly those in risk-bearing APMs, the clinicians participating in these innovative models need reassurances and protections that they will not be adversely penalized for participating in the very types of risk-bearing models that CMS has so strongly encouraged. If not, it could do irreparable damage to future confidence in the value-based payment reform movement.**

One-year Delay of MIPS Qualified Clinical Data Registry (QCDR) Measure Approval Criteria
CMS is delaying by one year QCDR measure testing and data collection requirements. QCDR measure developers now have until PY 2022 to fully develop and test new measures and collect complete testing results at the clinician level prior to submitting new measures for consideration. **ACP strongly supports the delay of QCDR measure testing and data collection requirements, which ACP previously expressed concerns over due to burden and likely delays in the development of new measures, problems that would only be exacerbated by the current COVID-19 PHE.**

Thank you for the opportunity to provide our input and recommendations around these important policy changes and flexibilities that are necessary to maintain and improve upon patient-centered care delivery now and after the conclusion of the PHE. Should you have any questions or need additional information, please contact Brian Outland, Director of Regulatory Affairs, at boutland@acponline.org.

Sincerely,

Ryan D. Mire, MD, FACP
Chair, ACP Medical Practice and Quality Committee