

June 16, 2020

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BY ELECTRONIC DELIVERY

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

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 CMS-5531-IFC

Dear Administrator Verma:

The National Health Council (NHC) is pleased to submit its comment to the above-referenced Interim Final Rule with Comment Period (IFR). The COVID-19 Public Health Emergency (PHE) has made it abundantly clear that, now more than ever, all people need access to adequate and affordable health care. The NHC continues to support the Administration's efforts to ensure that patients maintain access to the care they need without incurring increased out-of-pocket costs or compromising adherence to social distancing behaviors, which are particularly important for people with chronic conditions. We believe that the recently released set of additional policy and regulatory revisions contained in the IFR demonstrate the Centers for Medicare and Medicaid Services' (CMS') commitment to monitoring and responding to PHE-related burdens on health care resources and threats to patient health, safety, and access.

Created by and for patient organizations 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value,

sustainable health care. Made up of more than 140 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The NHC supported many of the flexibilities created in CMS' March 30, 2020 Interim Final Rule with Comment Period, particularly those related to allowing patients to receive care in their homes.¹ For patients with chronic diseases and disabilities, the risk of serious COVID-19 disease is particularly high, and the need to avoid exposure to the novel coronavirus will continue even when the general public moves toward resuming normal daily activities. Our comments remain focused on ensuring that the needs of patients and caregivers are met throughout the duration of the PHE and undoubtedly for an extended period afterwards, due to continued risk for people with chronic conditions after the PHE declaration expires. We:

- Support the Agency's expansion of access to and payment for telemedicine services;
- Urge CMS to implement mechanisms that protect Medicare patients from increased out-of-pocket expenses that might be associated with in-home administration of Part B drugs;
- Ask that CMS evaluate the impact of its PHE-related flexibilities, waivers, and policy refinements to identify those that best meet our shared goal of providing innovative health care and improving access to quality care while also reducing administrative burden; and
- Urge the Agency to leverage its enforcement authority to ensure that individuals suffering loss of income during the PHE do not lose access to affordable coverage through the exchanges.

The NHC supports the Agency's expansion of access to and payment for telemedicine services.

The NHC supports CMS' focus on increasing coverage of various avenues through which individuals can access needed health care. The IFR's provisions expanding and clarifying the telemedicine flexibilities announced in the March 30, 2020 IFR demonstrate CMS' ability to respond to patient and provider concerns quickly with practical solutions that enable patients to stay home when possible, while minimizing the burden on providers. As noted above, these flexibilities are particularly important for individuals with chronic conditions and disabilities who would otherwise face the added stress of choosing between the risk of potentially serious or fatal COVID-19 exposure

¹ <https://nationalhealthcouncil.org/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency/>

and the known consequences of discontinuing or postponing important treatments for their chronic conditions.

Permitting clinicians to perform telehealth visits, including evaluation and management services through audio-only devices.

We thank CMS for listening to stakeholders who urged equal payment for audio-only telehealth services. Access to devices with video capabilities is dependent on a number of factors, including financial wellbeing, broadband availability, and an individual's ability to navigate use of technology. Enabling clinician payment for audio-only services based on the breadth, scope, and duration of the encounter rather than the technology used will expand access to care.

Determining not to enforce the duration of remote physiologic monitoring (RPM) required to receive payment for RPM services furnished during the COVID-19 PHE.

Patients and caregivers have prioritized leveraging the Durable Medical Equipment (DME) benefit to expand remote physiological monitoring and other treatment options that enable patients to maintain careful control of their conditions within the safety of their homes. We agree that, for patients with a suspected or confirmed diagnosis of COVID-19, a monitoring duration of not less than two days is appropriate and urge CMS to extend the RPM duration flexibility to individuals with post-acute care needs as well as those with chronic conditions ordinarily requiring frequent in-person monitoring visits.

Expanding the types of providers and settings that can bill for telehealth services.

The NHC appreciates CMS' expansion of the types of providers and settings that can bill for telehealth services. Notably, we support CMS in its decisions to:

- Enable hospital outpatient departments to bill for telehealth services provided by hospital-based practitioners in Medicare outpatient settings, including when the patient is in their home;
- Include counseling and therapy services within the set of telemedicine-eligible hospital outpatient services;
- Clarify that rural health clinics and federally qualified health clinics can furnish services through telehealth; and
- Permit physical and occupational therapists and speech pathologists to offer services through telemedicine.

Using telehealth to treat opioid use disorder.

The NHC similarly supports CMS' efforts to ensure that individuals recovering from opioid use disorder through a program furnished by an opioid treatment program (OTP)

can continue to receive care without the risks associated with daily in-person clinic visits. Allowing OTPs to utilize audio-only telephone calls to deliver the therapy and counseling portions of the weekly service bundles, as well as the add-on code for additional counseling or therapy, should reduce disruptions in these crucial services. We agree that OTPs should use their clinical judgment and consider the individual needs of the patient in determining whether telemedicine modalities are adequate in performing periodic assessments within the patient's treatment plan.

Accessing Cardiac and Pulmonary Rehabilitation.

The NHC supports temporary, emergency coverage for telehealth-delivered cardiac and pulmonary rehabilitation (CR/PR) services during the COVID-19 pandemic when deemed appropriate by patients and their treating providers. At present, there is no mechanism for programs to be reimbursed for CR/PR services that are conducted remotely in the patient's home. Individuals with pulmonary and cardiovascular disease are among the most vulnerable to COVID-19, and as such should be afforded every opportunity to remain in their home when feasible. As CMS offers flexibility and payment mechanisms to allow for telehealth services for other patients, we ask that this same benefit be extended to CR/PR services.

The NHC urges CMS to implement mechanisms that protect Medicare patients from increased out-of-pocket expenses that might be associated with in-home administration of Part B drugs.

Access to Part B drugs was identified as a high-priority concern among patients and caregivers as the COVID-19 pandemic emerged. The NHC and its member communities applaud CMS for its swift action in leveraging telemedicine services to permit patients to continue their treatments through in-home administration when the risk of COVID-19 exposure outweighs the risks associated with treatment in the home setting. These flexibilities are particularly important for individuals with chronic diseases and disabilities who would otherwise have to risk a potentially serious or fatal exposure to the novel coronavirus to continue receiving life-saving treatments for their chronic conditions.

The NHC appreciates CMS' recognition that the decision on whether in-home administration is clinically appropriate should be made by the patient and their clinician based on the safety profile of the prescribed treatment, and individual patient and regional risk factors. Similarly, the Agency acknowledged that access to Part B drugs in the patient's home depends on provider willingness and ability to meet CMS' flexibilities with changes to their care delivery mechanisms, including entering into new contractual relationships to augment their ability to deliver care outside the physician office or hospital outpatient setting.

The NHC also appreciates that CMS created two separate paths through which patients can receive their Part B drugs in the safety of their homes, when appropriate.

Expanding the definition of “homebound” for purposes of eligibility for home care services to include patient-specific, PHE-related considerations was an important step toward preserving and protecting patients’ safe access to care and adherence to prescribed treatment regimens. We expect that patients could encounter situations where their home injections or infusions are billed under Part B through their treating physician in certain instances and performed by a home health agency with drug costs covered under Part D in other instances. Patients and caregivers remain concerned that the varying coverage and cost-sharing structures between Part B and Part D, including reliance on supplemental plans for Part B cost-sharing expenses, could significantly disadvantage patients. Individuals relying on the home health benefit and Part D coverage could encounter requirements to file for exceptions to access their current treatment and face financial burdens in the form of unexpected higher copays, coinsurance, and contributions toward the Part D deductible. We urge CMS to ensure that Medicare beneficiaries requiring Part B drugs do not face additional access barriers or financial burdens when their clinician determines that in-home administration is the safest alternative.

We ask that CMS evaluate the impact of its PHE-related flexibilities, waivers, and policy refinements to identify those that best meet our shared goal of providing innovative health care and improving access to quality care while also reducing administrative burden.

CMS’ series of initiatives to drive health care delivery system changes, while adapting to an evolving public health crisis, have been crucial in enabling providers to meet the challenges of this national emergency and serve their patients. For example, CMS cited a primary driver of its decision to eliminate the requirement that a physician order a COVID-19 test was that a significant number of Medicare beneficiaries do not have a relationship with a primary care provider. The PHE has highlighted access hurdles, including the lack of a primary care relationship, that many patients face when seeking medical care under ordinary circumstances, and these challenges will persist beyond resolution of the COVID-19 pandemic. These access hurdles contribute to and perpetuate health care disparities for minority populations, which has led to a disproportionate burden of chronic conditions, both in prevalence and in poorer health outcomes.²

We appreciate that CMS leveraged the urgency of the PHE to make permanent policy changes and clarifications, including:

- Permitting non-physician providers (physician assistants, nurse practitioners, certified nurse midwives, clinical nurse specialists, and others) to certify and order home health services, and review care plans for home health patients; and

² See, e.g., <https://www.kff.org/disparities-policy/issue-brief/disparities-in-health-and-health-care-five-key-questions-and-answers/> (March 4, 2020).

- Clarifying that pharmacists can work with a physician or other practitioner to provide assessment and specimen collection services and other services “incident to” a physician’s service. CMS anticipates that encouraging pharmacists to find new ways to work with physicians and non-physician providers will not only expand access to care during the PHE, but increase access to medication management services, particularly for individuals with substance use disorders.

We expect that the PHE accelerated CMS’ path toward broader adoption and utilization of telemedicine. The NHC urges the Agency to carefully examine the impact of these flexibilities on patient access to care, especially for those with chronic diseases and disabilities. Expanded access to telemedicine alternatives in minority, low income, and rural communities may hinge on CMS’ continuing implementation of PHE-related flexibilities such as permitting use of mobile telephones, including audio-only devices. Given recent estimates attributing approximately \$93 billion in excess medical care costs and \$42 billion in lost productivity per year to health care disparities, the NHC urges CMS to consider permanent adoption of telemedicine flexibilities that prove successful in expanding access to care during the PHE.³

We also urge the Agency to expand its stakeholder outreach during and after the PHE. Meaningful engagement with the patient and caregiver communities would enhance information already available to CMS through its claims database and increase the data needed to identify high-value telemedicine flexibilities that improve the outcomes patients care about most. To ensure that CMS and other stakeholders are best able to examine data and make recommendations, CMS should collect, report, and analyze demographic data, including race, gender, and disability status to better understand how the virus and various mitigation and care strategies impact these populations. The NHC and its members stand ready to help collect this data through tools like surveys, focus groups, and other methods.

The Agency’s responses to the PHE have also enabled it to identify and respond to system-wide inefficiencies, disparities, and care gaps that impede quality, cost-effective care. We urge CMS to continue its stakeholder engagement efforts to study and identify, as the nation begins to “re-open,” which temporary waiver and policy refinement provisions should be continued during the period between the PHE declaration expiration and widespread vaccine usage, protecting people with underlying health conditions. In particular, we want to assure that any permanent decisions are implemented in accordance with existing non-discrimination protections. Similarly, CMS should work with the stakeholder community, particularly patient advocacy organizations, to evaluate which provisions could permanently be implemented because they improve patient-centered care. Examples include:

³ Ani Turner, *The Business Case for Racial Equity, A Strategy for Growth*, (W.K. Kellogg Foundation and Altarum, April 2018), <https://altarum.org/publications/the-business-case-for-racial-equity-a-strategy-for-growth>.

- Examining the impact of suspending prior-authorization requirements in Medicaid, Medicare Part D, Medicare Advantage, and exchange plans on non-COVID-19 drug and plan administration costs. Identifying therapeutic categories and disease states for which utilization management tools increase patient and provider burden without a proportional cost reduction would enable plans to more appropriately focus those utilization management efforts;
- Reviewing the impact that CMS' suspension of documentation requirements associated with oxygen equipment and other DME has had on costs for those items and supplies, enhancing CMS efficiencies in managing the DME benefit; and
- Streamlining any other protocols and policies that could increase access to care.

The NHC also believes that the waivers adopted within the Medicaid program to facilitate care across state lines strike an appropriate balance between patient access to care and the programmatic requirements that ensure Medicaid providers are screened and qualify to provide services.

The NHC urges the Agency to leverage its enforcement authority to ensure that individuals suffering loss of income during the PHE do not lose access to affordable coverage through the exchanges.

The COVID-19 pandemic has underscored the fact that all people need access to adequate and affordable health care, both to address acute illness and to manage chronic conditions that too often lead to poor outcomes and higher health care costs. Research has demonstrated that access to comprehensive health insurance is required to access timely, medically necessary health care. If someone without health insurance today contracts the COVID-19 virus, they may be forced to make the difficult decision to not be tested and treated due to fears about the cost of care, compounded with the lost income associated with protracted illness. It not only perpetuates the risk to individuals with chronic diseases and disabilities but puts at risk the safe and permanent return to normal activities required for a strong economic recovery.

The economic impact of COVID-19 is likely to persist well beyond the PHE. Medicaid enrollment is projected to increase anywhere from 11 to 23 million over the next several months as a result of COVID-19 and its economic impact.⁴ Eleven states and the District of Columbia have opened their marketplaces so that individuals can obtain health insurance, and tens of thousands of Americans in these states have already

⁴ COVID-19 Impact on Medicaid, Marketplace, and the Uninsured by State. Health Management Associates. April 3, 2020. Accessed at: <https://www.healthmanagement.com/wp-content/uploads/HMA-Estimates-of-COVID-Impact-on-Coverage-public-version-for-April-3-830-CT.pdf>

taken advantage of this opportunity. States relying on the federal exchange, however, do not have the authority to open enrollment for their citizens, who may experience both a loss of income and an inability to enroll in sufficient health care coverage. And individuals with preexisting conditions may find it all but impossible to secure comprehensive coverage for their chronic disease or disability unless and until they secure an employer-sponsored insurance plan.

Although most states have expanded their Medicaid programs to eliminate any gaps between income qualifications for Medicaid and the lower limits of income required to enroll in a subsidized marketplace plan, the current unprecedented rates of unemployment and underemployment threaten to create a significant set of newly uninsured working-class families. Many of these individuals will find that their income falls above the threshold for Medicaid eligibility in states that have not expanded Medicaid, but their income is too low to be eligible for advanced premium tax credits, forcing them to pay the entire premium. The benefits of ensuring continuing coverage for these individuals are clear, including improved access to coverage and positive health outcomes for patients, as well as economic benefits to states and hospitals.⁵ The NHC urges CMS to utilize its enforcement discretion and administrative authority to:

- Waive continuous coverage requirements for marketplace enrollees with respect to coverage gaps, including those associated with loss of employer-sponsored coverage;
- For individuals and families unable to meet Medicaid eligibility requirements, waive requirements that marketplace enrollees meet minimum income requirements to qualify for subsidized plan enrollment. Americans should not be penalized for losing income during the PHE;
- Implement strong risk mitigation policies with sufficient oversight to ensure premiums do not rise in the wake of the pandemic. Individuals and families relying on marketplace coverage should not bear the financial burden of the pandemic and have to choose between meeting ongoing financial obligations within a fragile economy and retaining insurance coverage;
- Open a special enrollment period (SEP) for the Federal health care exchange;
- Assure that those individuals cycling on to exchange plans have sufficient education and guidance through tools such as Navigators; and

⁵ <https://www.kff.org/medicaid/report/the-effects-of-medicaid-expansion-under-the-aca-updated-findings-from-a-literature-review/>

- Implement a moratorium on implementation of barriers to gaining and maintaining Medicaid coverage, including state waivers establishing work requirements, eliminating retroactive eligibility, or increased cost sharing.

Conclusion

Once again, the NHC appreciates the opportunity to support CMS as it continues to respond to this unprecedented public health crisis. Please do not hesitate to contact Eric Gascho, the National Health Council's Vice President of Policy and Government Affairs, if you or your staff would like to discuss these issues in greater detail. He is reachable by phone at 202-973-0545 or via e-mail at egascho@nhcouncil.org.

Sincerely,

A handwritten signature in black ink, appearing to read "MBoutin", with a long horizontal stroke extending to the right.

Marc Boutin, JD
Chief Executive Officer National Health Council