

June 1, 2020

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1744-IFC
P.O. Box 8016
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (Interim Final Rule) (CMS-1744-IFC).

Dear Administrator Verma:

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Interim Final Rule*. NCPA represents America's community pharmacists, including 21,000 independent community pharmacies. Almost half of all community pharmacies provide long-term care services (LTC) and play a critical role in ensuring patients have immediate access to medications in both community and LTC settings. Together, our members represent a \$76 billion healthcare marketplace, employ approximately 250,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

NCPA appreciates CMS' willingness to act imminently and appropriately on the COVID-19 public health emergency (PHE). In this Interim Final Rule, CMS acknowledges that Star Ratings may be impacted by the PHE and thus has afforded several flexibilities in collecting data that is relevant to those calculations. We ask that CMS acknowledge that this leniency may not be afforded to pharmacies or provider groups in those contracts with plan sponsors and asks CMS to indicate that any relief should be afforded to pharmacies and other provider groups as well.

We also bring CMS' attention to the continuous and heightened impact of direct and indirect remuneration (DIR) fees on our members. Pharmacy DIR fees are growing beyond CMS' projection of 10% year-over-year.¹

¹ Centers for Medicare and Medicaid Services, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*, Proposed Rule (Nov. 30, 2018), available at <https://www.govinfo.gov/content/pkg/FR-2018-11-30/pdf/2018-25945.pdf>, [hereinafter "CMS Part D Drug Pricing Proposed Rule"].

In fact, a recent NCPA analysis showed that 66 percent of independent pharmacies are experiencing negative cash flow issues such as DIR fees, decreasing reimbursement, and coronavirus-related expenses.² That means pharmacies are paying more for inventory and DIR clawback fees, which makes it difficult to stay in business. Half of pharmacy owners reported paying more than \$10,000 in pharmacy DIR fees since March 1, 2020. If this pace continues, the average independent pharmacy will be on track to have over \$100,000 clawed back in the next 12 months. This growth of DIR fees is especially unsustainable during the current COVID-19 PHE as it is leading to pharmacy closures during a critical time. **We strongly ask CMS to finalize the portion of the 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule³ pertaining to *pharmacy price concessions in the negotiated price* as soon as possible to help alleviate DIR fees.**

1. Payment for Medicare Telehealth Services

Describes payment amounts and conditions under which Medicare will pay for certain services, which must ordinarily be furnished in person, when they are instead provided through telehealth (list of telehealth-eligible services available on CMS website [here](#)). Geographic limitation on telehealth services waived, can now be provided anywhere in the country, including at home. Also waiving on an interim basis frequency limitations and other requirements associated with particular services furnished via telehealth.

NCPA supports the use of telehealth for delivering clinical health and person-centered care, particularly in rural health areas, and especially during times of national, state, and local emergencies (e.g., COVID-19 pandemic outbreak). Pharmacists are a part of the health care management teams providing Medicare services, including telehealth. The technology for exchanging COVID-19 information from a telehealth visit is available through pharmacy management systems. Telehealth enables pharmacists to connect with established health care management teams and patients, particularly when questions arise concerning medications prescribed or changes to medications, independent of geography. **In many instances, especially in rural and underserved areas where telehealth would be invaluable, pharmacists are the first point of contact by patients and their caregivers.**

Community pharmacists can provide telehealth benefits, especially during COVID-19 when the need for telehealth is heightened. Such services include, but are not limited to, medication therapy management (MTM), chronic care management, transitions of care, pharmacogenomics, interpretation of diagnostic tests and providing test results, consultations with patients and health care providers, and ambulatory care services.

² NCPA, *Report for Pharmacy Economic Health: Coronavirus Pandemic Survey* (April 2020), available at https://ncpa.org/sites/default/files/2020-04/4.20.2020-Survey-Results_0.pdf.

³ *CMS Part D Drug Pricing Proposed Rule.*

Telehealth is also a cost-saving option that can expand pharmacist-provided health care services to patients, while complementing existing pharmacy services. Telehealth and telepharmacy could also provide cost-savings for hospitals, particularly rural hospitals.⁴

Under the current Medicare Telehealth Benefit, however, pharmacists are not recognized as practitioners. This means there are no Medicare payment codes for pharmacist-provided telehealth services and Medicare does not reimburse pharmacists for the telehealth services provided. Although Medicare routinely pays physicians and other health care providers and practitioners (i.e., social workers, dieticians)⁵ for several kinds of services provided via interactive communication technology, NCPA believes pharmacists should also be paid for the telehealth services they provide, especially during a PHE such as COVID-19. **NCPA urges CMS to recognize and ensure payments to pharmacists when billing for telehealth services.**

2. Clarification of Homebound Status under the Medicare Home Health Benefit

Patients who are instructed to remain in their homes or are under self-quarantine are considered confined to the home or homebound for purposes of the Medicare home health benefit where a physician has determined that it is medically contraindicated for a beneficiary to leave the home; patient who is self-quarantined for their own safety are not considered confined to the home unless a physician certifies that it is medically contraindicated for the patient to leave the home.

NCPA would like to reiterate and emphasize our ask to CMS that medical at home pharmacy services are needed now more than ever due to the PHE. Since April 2019, NCPA has been corresponding with CMS on this issue and continues to stress the importance of CMS' recognition of these services. This demand for at-home care was on the rise before the deadly coronavirus outbreaks in nursing facilities across the country. Looking beyond the pandemic, demand will only continue, increasing as seniors who need specialized care continue to socially distance due to their increased risks and vulnerabilities. **To meaningfully address the increasing aging population who require assistance with activities of daily living, especially during the COVID-19 crisis, we urge CMS to recognize medical at home pharmacy services and issue guidance formally recognizing these services at the same level as other LTC services.**

The medical at home model represents a shifting population of patients preferring to receive the same care they would receive in an LTC facility in their homes, which is a lower cost environment. LTC pharmacists are providing the same valuable services they are providing to skilled nursing patients, but the services are being delivered in the patient's home, due to their need for extra clinical services.

⁴ Health IT News, January 2018, <https://www.healthcareitnews.com/news/telepharmacy-rural-hospitals-provides-big-savings-quality-improvements>

⁵ See 42 C.F.R. §410.73 and §410.134.

NCPA asks that CMS recognize medical at home pharmacy services regardless of where the patient resides and issue guidance formally recognizing patient residence code “01” (home) with level of service “7” (medical at home) at the same level as patient residence code “3” (nursing facility) or “9” (intermediate care facility/mentally retarded).

The National Council for Prescription Drug Programs (NCPDP) has also been discussing medical at home pharmacy services via its Work Group 14 LTPAC Billing Issues Task Group. NCPDP approved one new level of service referencing medical at home services with special pharmacy services identical to those provided to LTC nursing facility beneficiaries (not including emergency kits). In August 2020, NCPDP members are expected to approve an addition to the billing standard FAQ, drafted by members of an LTPAC billing task group, for how to communicate on a claim transaction that the patient is receiving LTC services when the patient does not reside in an LTC setting. Within this FAQ, NCPDP has included an answer stating that these services can be communicated on a claim by using the appropriate Patient Resident Code (484-DX) and a Level of Service Code (418-DI) value of “7” (Medical at home with special pharmacy services identical to Long Term Care beneficiaries with the exception of emergency kits). Evidently, industry is moving towards formally including medical at home pharmacy services as skilled services, but payment for these services cannot occur until CMS provides guidance to plans and PBMs to recognize these services at a higher level of care.

Due to the imminent need for medical at home pharmacy services and NCPDP’s progression on the FAQ above, we ask that CMS formally recognize and promote medical at home pharmacy services to help improve value-based patient care during the COVID-19 PHE, increase savings to the health care system, and ensure pharmacy providers are fairly and properly reimbursed for their services. As such, NCPA urges CMS to issue guidance to Part D plans recognizing these services at the same level as LTC services and to update the Medicare Part D Manual to include patients residing at their home as patients receiving a higher level of care.

3. Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing

\$5.00 fee for specimen collection from certain individuals in skilled nursing facilities (SNFs) or by a laboratory on behalf of an HHA will be increased to \$23.46 for COVID-19 testing for homebound and nonhospital inpatients during the PHE. Fee is increased to \$25.46 for individuals in an SNF or individuals whose samples will be collected by a laboratory on behalf of an HHA. Collecting specimens (including sputum samples) using nasopharyngeal or oropharyngeal swabs will require a trained laboratory professional, which is a condition to payment of the specimen collection fee. Two new HCPCS codes (G2023 and G2024, collections from an individual in an SNF or by a laboratory on behalf of an HHA) to identify specimen collection for COVID-19 testing. Proper documentation of miles traveled not required and laboratories can maintain electronic logs for travel fees during the PHE for nonhospital inpatients and homebound patients.

NCPA appreciates HHS' and CMS' recent guidance authorizing pharmacists to bill for COVID-19 tests. As NCPA understands, there are currently two pathways for pharmacists to bill Medicare for COVID-19 testing. The first mechanism is where the pharmacy must enroll as an independent clinical lab. A pharmacy that acquires a CLIA Certificate of Waiver can enroll with Medicare as an independent clinical lab to conduct and bill for clinical lab tests it is authorized to perform under its CLIA certificate. We further understand that these COVID-19 point of care tests must be approved for a "patient care setting" under an emergency use authorization (EUA) by FDA. In terms of specimen collection, NCPA understands that Medicare will only allow specimen collection billing under this pathway for pharmacies enrolled as independent clinical labs for collecting specimens from beneficiaries who are homebound or inpatients not in a hospital for COVID-19 testing, **not** specimens collected in these pharmacies.

The second pathway CMS has indicated pharmacies can provide COVID-19 testing under is through Medicare Part B's incident to structure. Under this pathway, pharmacists can provide services incident to the professional services of a physician or nonphysician who bills Medicare Part B under the Physician Fee Schedule (PFS) services, if incident to rules are met and payment for the services is not made under Medicare Part D. This includes assessing and collecting specimens for COVID-19 diagnostic tests. On an interim basis, NCPA understands that CMS will use CPT code 99211 for a level 1 evaluation and management (E/M) visit for the purpose of a COVID-19 assessment and specimen collection, that can be billed by physicians for pharmacists' basic clinical services for both new and established patients under incident to physician services arrangements.

CMS also recommended that pharmacists may want to establish a private contract with the limited amount of labs in the country with high-throughput technologies developed by the private sector that allow for increased testing capacity, faster results, and more effective means of combating the spread of the virus. CMS would not be involved in these contracts, and Medicare would pay the higher payment of \$100 for COVID-19 clinical lab tests making use of high-throughput technologies.

As stated above, NCPA appreciates CMS' flexibilities in expanding pharmacists' ability to provide and administer COVID-19 testing. **We ask that CMS create a direct pathway for pharmacists to bill for specimen collection and related testing services for patients who come to their pharmacies. Our members are not set up and cannot scale up in time to have incident to or lab relations in place to address the imminent needs of the PHE.**

4. Innovation Center Models

Medicare Diabetes Prevention Program (MDPP): During the PHE, CMS is permitting: 1) certain beneficiaries to obtain the set of MDPP services more than once per lifetime; 2) an increase in the number of virtual make-up sessions; and 3) certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis. These changes are generally applicable to beneficiaries who were receiving MDPP services on March 1. Requirement for a beneficiary to attend the first core session remains in effect.

NCPA commends CMS for modification of certain Medicare Diabetes Prevention Program (MDPP) expanded model policies during the COVID-19 PHE. In particular, policy modifications that: 1) allow certain beneficiaries to obtain the set of MDPP services more than once per lifetime 2) allow MDPP suppliers to offer MDPP beneficiaries virtual make-up sessions; and 3) waive the limit to the number of virtual make-up sessions ensure that beneficiaries have access to MDPP services during the COVID-19 PHE. Pharmacists are a critical partner in the effort to prevent new cases of type 2 diabetes among patients at high risk, and **NCPA applauds these temporary flexibilities that will increase the likelihood that participants will maintain healthy behaviors and successfully meet model goals.**

5. Remote Physiologic Monitoring (RPM)

Providers may offer RPM services to both new and established patients during the PHE for both chronic and acute conditions.

Diabetes requires close monitoring to achieve optimal outcomes and avoid adverse effects, and continuous glucose monitoring (CGM) is an approach to measuring glycemia that has become widespread with recent advances in technology. Many CGMs are available through pharmacy benefits, and pharmacists have been at the forefront of implementing CGM technology, teaching patients how to use their devices and understand data. RPM services support recommendations from the Centers for Disease Control and Prevention (CDC) goal of reducing human exposure to the novel coronavirus while also increasing access to care and improving patient outcomes. NCPA would appreciate CMS clarification on whether CGM are included in the definition of RPM for the purposes of offering RPM services to both new and established patients during the COVID-19 PHE for chronic conditions. If the current definition of RPM does not include CGM, **NCPA urges CMS to consider RPM to be inclusive of CGM during the COVID-19 PHE, particularly given the benefits CGM has over traditional glucose monitoring.**

6. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

NCPA commends CMS in addressing the impact of the COVID-19 pandemic on Part C and D Quality Rating Systems. NCPA also appreciates CMS making modifications to the calculation of 2021 and 2022 Part C and D Star Ratings to address the extended impact of the COVID-19 PHE on data collection and performance. However, NCPA cautions against any flexibilities for plan sponsors regarding Star Ratings coming at the expense of pharmacy providers whose performance in response to the pandemic may compromise their Star Rating system performance. Although these Star Ratings flexibilities are directed towards plan sponsors, the downstream impact on pharmacies is undeniable. **NCPA urges CMS to acknowledge that this leniency may not be afforded to pharmacies or provider groups in those contracts with plan sponsors and asks CMS to acknowledge that any relief should be afforded to pharmacies and other provider groups as well.**

Further, the provisions in this section address the immediate needs of plan sponsors to focus on providing care to Medicare beneficiaries who are impacted by COVID-19. **We urge CMS to continue monitoring the impact of the PHE for the remainder of 2020 and into 2021 to determine whether additional Star Rating changes are necessary as the pandemic evolves.**

a. Adjustments to the 2021 Star Ratings Methodology Due to Lack of HEDIS and CAHPS Data

NCPA supports CMS' modifications to the 2021 Star Ratings, using data from the 2020 Star Ratings for measures based on Health Effectiveness Data and Information Set (HEDIS) and Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) data (i.e. HEDIS data from the 2018 measurement year and CAHPS data from June 2019).

b. Use of 2020 Star Ratings to Substitute for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues

In the event of extraordinary compromised CMS capabilities or systemic data issues, NCPA supports the use of the MTM Program Completion Rate for Comprehensive Medication Review measures' scores and stars from the 2020 Star Ratings as the sponsors' 2021 Star Ratings on the measure.

c. 2022 Star Ratings

i. CMS Delaying Implementation of Guardrails

NCPA appreciates CMS' anticipation of an impact on performance for the 2020 measurement period (for 2022 Star Ratings) as plan sponsors and their providers adapt their current care practices in response to the COVID-19 pandemic in caring for the most vulnerable patients, such as the elderly and those with chronic health conditions.

NCPA supports CMS delaying the implementation of the guardrails for the 2022 Star Ratings, so that cut points can decrease by more than 5 percentage points if national performance declines resulting from the pandemic. However, **NCPA recommends that CMS monitor the impact of delaying implementation of the guardrails in the event that national performance improves for some measures during the 2020 measurement period.** For example, plans may observe an improvement on performance of the MTM Program Completion Rate for Comprehensive Medication Review measure with many beneficiaries sheltering in place. Additionally, adherence measure performance could be inflated if the flexibilities granted to plans during the PHE to relax "refill-too-soon" edits and extend days' supply for Part D drugs results in beneficiaries stockpiling medications. If national performance improves for some measures, this could disproportionately impact health and drug plans impacted more heavily by COVID-19.

ii. **CMS Revising the Methodology for the Part C and Part D Improvement Measure for the 2022 Star Ratings to Expand the Hold Harmless Rule to Include All Contracts at the Overall and Summary Rating Levels.**

NCPA supports CMS' revised methodology for the Part C and D improvement measure for the 2022 Star Ratings to expand the hold harmless rule to include all contracts at the overall and summary rating levels, recognizing that the PHE and COVID-19 pandemic may result in a decline in industry performance. In addition, NCPA urges CMS to pass down the hold harmless rule flexibilities to those in the supply chain that may be affected by downstream impact, such as pharmacies. **For any hold harmless provision that is extended to plans, NCPA asks CMS issue recognition and guidance that these flexibilities be passed on to pharmacies as well.**

d. **Anticipated Impact of COVID-19 on Statin Use in Persons with Diabetes**

COVID-19 is likely to have an impact on performance on the Statin Use in Persons with Diabetes (SUPD) measure. With shelter-in place orders in many areas and healthcare facilities rescheduling non-urgent outpatient visits, access to primary care providers may be limited. Even with the promotion of telehealth visits, starting a statin typically involves baseline laboratory data, such as liver function tests. Delaying the implementation of the guardrails and expanding the hold harmless rule for the Part C and D improvement measure for the 2022 Star Ratings will be helpful in mitigating the impact of the pandemic. **However, given that the SUPD measure will be triple weighted for the 2022 Star Ratings, CMS may want to consider additional steps to mitigate the impact on of COVID-19 on measure performance.** One option to consider would be to expand the hold harmless rule to the SUPD for the 2022 Star Ratings, applying the higher of the Star Ratings from Rating Year 2021 or 2022.

e. **Geographic Variation of COVID-19**

NCPA encourages CMS to consider that the prominent geographic variation of COVID-19 and local responses to the pandemic could translate to disparate impact on some geographic areas being more impacted than others and whether additional Star Ratings adjustments are necessary and appropriate. The geographic variation of the impact of COVID-19 could be further compounded by sociodemographic factors that impact pharmacy measure performance. We are supportive of implementation of the PQA-developed risk adjustment methodology for sociodemographic status factors for the three medication adherence measures used in the Medicare Part D Star Ratings Program.

f. **Social Determinants of Health**

Even prior to the pandemic, many health and drug plans have implemented initiatives to address social determinants of health (SDOH) and social isolation. COVID-19 provided a critical opportunity to connect with members through MTM interventions to combat loneliness, food insecurity, behavioral health, access to care, and costs.

For comprehensive medication reviews (CMRs) and other outreach, some plans are using SDOH and COVID-19-specific questions to identify members at risk. This provides an opportunity to refer beneficiaries to case managers, behavioral health services, or other needed services. **NCPA suggests that a standard set of questions could be used in MTM sessions that identify SDOH barriers to access and adherence.**

g. Value-Based Arrangements

As stated above, although the Part C and D Star Ratings are for rating the Medicare health and drug plans (not pharmacies), the downstream impact of the program on the healthcare system is undeniable, including the contractual arrangements between plans and provider groups or pharmacies. **NCPA is concerned about whether the changes made by CMS in response to COVID-19 for the 2022 Star Ratings for health and drug plans will translate to commensurate modifications to their contractual value-based arrangements. We recommend that CMS continue to monitor the impact of COVID-19 on the entire healthcare system.**

While monitoring the impact of COVID-19, we also urge CMS to evaluate the impact of pharmacy DIR fees on our members during this critical time of the COVID-19 crisis. Although we appreciate HHS' effort to-date to attempt to end the retroactive nature of DIR fees pharmacies still need a regulatory fix. As stated above, DIR fees have soared in recent years, estimated to exceed \$100,000 per pharmacy in the next year.⁶ Pharmacy benefit managers (PBMs) continue to assess these fees in an unreasonable manner on pharmacies and this has continued to cause community pharmacies to close. In fact, a recent NCPA analysis showed that 66 percent of independent pharmacies are experiencing negative cash flow issues such as DIR fees, decreasing reimbursement, and coronavirus-related expenses. Due to the critical need for pharmacy participation during the COVID-19 PHE, and to prevent further pharmacy closures, **we strongly ask CMS to finalize the portion of the 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule⁷ pertaining to *pharmacy price concessions in the negotiated price* as soon as possible.**

7. Advance Payments to Suppliers Furnishing Items and Services under Part B

NCPA supports allowing advanced payments during the COVID-19 PHE to suppliers who request them, such as pharmacists who are furnishing items and services under Part B.

8. Conclusion

NCPA greatly appreciates the opportunity to share our comments and suggestions on CMS' Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (Interim Final Rule).

⁶ NCPA, *Report for Pharmacy Economic Health: Coronavirus Pandemic Survey*.

⁷ *CMS Part D Drug Pricing Proposed Rule*.

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NCPA is committed to working with CMS and other industry stakeholders in ensuring that pharmacists' ability to provide COVID-19 testing is maximized, medical at home pharmacy services are recognized, and pharmacy performance measures are not negatively impacted by the Interim Final Rule's Star Ratings changes.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ronna B. Hauser".

Ronna B. Hauser, PharmD
Vice President, Policy & Government Affairs Operations
National Community Pharmacists Association