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Impact of regulatory changes on pharmacist-delivered telehealth during the COVID-19 pandemic

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The 2020 coronavirus disease (COVID-19) pandemic in the United States has created a dramatic need for the rapid implementation of telehealth services in areas of the country where telehealth is limited in scope.¹ This implementation would not have been possible without major changes in how the Centers for Medicare and Medicaid Services (CMS) provide reimbursement for telehealth. In this brief review, we intend to evaluate the regulatory changes that have taken place, the impact of these changes, and the additional opportunities for outpatient pharmacists to receive compensation while providing distant health care.

Traditionally, the Health Resources and Services Administration defines telehealth as the use of electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health related education, public health, and health administration.² Before the implementation of COVID-19 waivers, access to telehealth services for Medicare patients was mostly restricted to areas of the country defined as nonmetropolitan statistical areas (MSA) or rural Health Professional Shortage Areas. Some exceptions to these location requirements were made for patients with end stage renal disease, acute stroke, and substance use disorder with concomitant mental health conditions. In addition to location restrictions, Medicare also requires that Medicare telehealth appointments are delivered through synchronous audio and visual telecommunication that permit real-time communication, use a platform that is considered Health Insurance Portability and Accountability Act (HIPAA) compliant, and take place between providers with an established patient and provider relationship.³ Medicare and private insurers have also reimbursed for telehealth services at a reduced rate. These restrictions combined with reduced compensation have contributed to telehealth services being a nonpreferred option for many providers.

In 2019, CMS lifted some restrictions to telehealth and began reimbursing providers for services that used additional telecommunication approaches, which included virtual check-ins, remote evaluation of prerecorded patient information, and interprofessional Internet consultations. A virtual check-in is a brief communication delivered synchronously with an established patient and is intended to be patient-initiated access to care. Remote evaluation of prerecorded information is a brief communication delivered synchronously with an established patient and is intended to be patient-initiated access to care. Remote evaluation of prerecorded information is a brief communication delivered synchronously with an established patient and is intended to be patient-initiated access to care. Interprofessional Internet consultations are a pathway for providers to seek...
reimbursement when the consultation occurs through telephone or asynchronously through the Internet. This consultation awards compensation only to the provider who is being consulted. In addition, these services do not have the same location restrictions as mentioned for other Medicare telehealth services. Unfortunately, none of these newer telehealth services or standard Medicare telehealth services allow the pharmacists to seek compensation for their time.3

Although compensation challenges make it difficult for the pharmacists to use telehealth, they have still been engaged in providing these services to patients. When providing telehealth services, pharmacists have shown a statistically significant impact on patient-centered outcomes. In 2012, McFarland et al. showed that in patients accessing clinical pharmacy services through telehealth, there was a statistically significant difference between patients achieving glycosylated hemoglobin goals at 3 months and 6 months compared with the patients who did not use telehealth when accessing pharmacy services. Improvements in patient-centered outcomes have also been observed with management of hypertension; a 2013 study by Margolis et al. showed that in comparison with the usual patient care, telehealth monitoring of patient’s blood pressure by pharmacists improved control at 6, 12, and 18 months. Pharmacists have shown also shown statistically significant improvements in patient-centered outcomes in readmissions for chronic obstructive pulmonary disease and heart failure exacerbations, control of international normalized ratio, achievement of tobacco cessation, and the use of lipid lowering medications. These documented improvements in outcomes show that the use of telehealth not only improves patient care, but also that pharmacists are successful at implementing it.

In response to the COVID-19 pandemic, the CMS took action on March 17, to expand access to telehealth services through a waiver to Section 1135 of the Social Security Act, which allows for temporary modifications to Medicare, Medicaid, and the Children’s Health Insurance Program during a national emergency. Under this waiver, CMS authorized the delivery of Medicare telehealth services throughout the nation. This waiver allowed designated providers to deliver services that would otherwise occur in person through telehealth at a regular and not a reduced rate of reimbursement. In addition, CMS stated that the Department of Health and Human Services (HHS) would not conduct audits that targeted the verification of established relationships between a provider and a patient. With the expected expansion of Medicare telehealth appointments owing to these changes, CMS also announced that the HHS office for Civil Rights would be exercising enforcement discretion and waive penalties for HIPAA violations against providers serving patients in good faith through everyday communication technology, which allows the providers to use services such as FaceTime, Skype, and Zoom to complete the Medicare telehealth services. In addition to expanding access to Medicare telehealth services, CMS also emphasized that providers may continue to use virtual check-ins and e-visits. For many providers, using these options is important because unlike Medicare telehealth services, there is no requirement for both real-time audio and visual communication, but simply a synchronous discussion for a virtual check-in, or an asynchronous discussion for an e-visit. The lack of need for both real-time audio and visual communication allows a provision for these services through a broader range of communication modalities, including the use of patient portals, telephones, and secure text messaging. Both e-visits and virtual check-ins are specific telehealth provisions and are reimbursed at their own rates.

Unfortunately, despite the implementation of waivers that allow physicians; nurse practitioners; and qualified nonphysician health professionals such as physicians’ assistants, physical therapists, and clinical social workers, to continue providing a wide range of services for their patients, and pharmacists appear to be mostly excluded from these federal provisions. As outpatient pharmacists may use an “incident-to” model to bill their services, it has been questioned if this would continue to be feasible, given the lack of specific mention of pharmacists as eligible telehealth providers in the aforementioned waivers. On March 30, CMS released an updated guidance document providing clarification on some “incident-to” requirements, and included that direct supervision would be allowed through the use of real-time audio and video technology. Under normal circumstances, direct supervision would require the billing provider to be available in the same location as the service. In addition, CMS indicated that providers can enter into a contractual arrangement with auxiliary personnel, which includes pharmacists, to ensure continued delivery of services provided “incident-to” a physician’s service. Unfortunately, this guidance did not change the eligibility of pharmacists to be compensated for telehealth services under Medicare. So, despite changes to supervision requirements and reinforcement that the pharmacists are considered as auxiliary personnel, the ability of pharmacists to be compensated for telehealth services remains limited. National pharmacy organizations have taken note of this and are advocating for changes. On April 6, the American Pharmacists Association contacted CMS administrator Seema Verma advocating for the HHS Secretary Alex Azar to use the new authority granted under the Coronavirus Aid, Relief, and Economic Security Act to include pharmacists in telehealth provisions. However, as of May 18, 2020, no additional changes to existing law have taken place that specifically allow pharmacists to receive compensation for the necessary services delivered through telehealth.
Table 1
Potential telehealth compensation options for pharmacists

| Category     | CPT code | Summary of code                                                                 | Approximate reimbursement11 |
|--------------|----------|---------------------------------------------------------------------------------|----------------------------|
| CCM          | 99490    | CCM services, at least 20 min of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: Multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient. Chronic conditions place the patient at a significant risk of death, acute exacerbation or decompensation, or functional decline. Comprehensive care plan established, implemented, revised, or monitored assumes 15 min of work by the billing practitioner per month. | $42.22                      |
|              | 99487    | Complex CCM services, with the following required elements: Multiple (2 or more) chronic conditions expected to last at least 12 months, or until the death of the patient. Chronic conditions place the patient at a significant risk of death, acute exacerbation or decompensation, or functional decline. Establishment or substantial revision of a comprehensive care plan. Moderate or high complexity in medical decision making. 60 min of clinical staff time directed by a physician or other qualified health professional, per calendar month. | $92.39                      |
| CGM          | 95251    | Ambulatory CGM of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 h; analysis, interpretation, and report. | $36.81                      |
| Anticoagulation | 93793 | Anticoagulation management for patients taking warfarin. Must include review and interpretation of a new home, office, or lab international normalized ratio test results, patient instructions, dosage adjustment (as needed), and scheduling of additional test(s), when performed. | $11.91                      |

Abbreviations used: CCM, chronic care management; CGM, continuous glucose monitoring.

Regulatory hurdles will continue to impact pharmacists’ ability to deliver telehealth until they are recognized as providers under Title XVII of the Social Security Act, which established Medicare. However, lack of provider status does not mean that the pharmacists’ cannot continue to provide high-quality patient care and be compensated for the high-quality care they provide. Many Medicare patients, who receive chronic disease state management by pharmacists, are likely to be eligible for chronic care management (CCM). In 2015, Medicare began to compensate providers for their efforts in managing a patient’s chronic disease state through CCM. Under this program, pharmacists who are either directly employed by the clinician or are contracted as third party and whose services are generally supervised by a clinician, may be considered as clinical staff time for CCM billing purposes. What is of particular importance during the COVID-19 pandemic is that direct supervision, which as stated above is required for “incident-to” billing, is not a requirement for CCM. Instead, a general supervision is allowed when care is delivered under the direction of a provider, but their physical presence is not required. This flexibility may provide an avenue for the pharmacists to continue disease state management through collaborative practice agreements when providers and patients are unable to be present because of the ongoing COVID-19 pandemic. In addition to CCM, pharmacists can also consider using disease state specific codes that allow for the remote evaluation of patient data. Specifically, these are available for patients who are on anticoagulants or are using continuous glucose monitoring. These were available before COVID-19 but might not have been used with other current procedural terminology (CPT) codes that provided higher rates of reimbursement for patients when seen in person. Given the limitations in using “incident-to” billing during this crisis, Table 1 identifies some of the aforementioned CPT codes with the approximate level of reimbursement and general requirements. With compensation options being limited, pharmacists may also take advantage of the situations where they can work in collaboration with other health care providers to deliver care. As many providers have switched to telehealth models, outpatient pharmacists can use this as an opportunity to work in interdisciplinary teams to continue providing the high-quality patient care that they were providing before COVID-19. While pharmacists may not directly bill for these services, the impact of their skills in direct patient care should not be lost.

While CMS has made limited changes to the pharmacist’s ability to deliver telehealth, some states, including Arizona, Illinois, and North Carolina, have been specific in their orders that pharmacists are considered as providers who can deliver telehealth services. North Carolina has also been specific to ensure that clinical pharmacists are considered to be eligible distant site telemedicine providers, wherein they may provide telehealth services from any location during the pandemic. While not all states have been specific in considering pharmacists as providers, a number of states consider pharmacists as providers and the wordings of the executive orders or Medicaid directives would therefore include pharmacists as eligible to deliver telehealth services. Despite this, several states do not include pharmacists in COVID-19 related waivers or executive orders, which may create an unnecessary burden as the pharmacists seek to continue the delivery of care to patients who require it. For continued updates on changes in the state and federal regulations as it relates to telehealth and the COVID-19 pandemic, we suggest using resources found at the Center for Connected Health Policy. Their website contains a routinely updated compilation of all the regulatory announcements on this subject, at both the federal and state levels.

Pharmacists provide high-quality care that directly impacts the lives of many patients in this nation. As the nation expands the delivery of care with the telehealth model during the COVID-
19 pandemic, pharmacists are excluded from seeking compensation for the care they provide. While some reimbursement options remain open to pharmacists, they depend on local regulation or the ability of a site to alter their practice. This overview of the regulatory changes shows that despite strides in telehealth service compensation for health care providers, pharmacists continue to lack the ability to seek appropriate compensation for their direct patient care services.

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