COVID-19: NAVIGATING THE PATH TO RECOVERY - PLANNING FOR LIFE AFTER 1135 WAIVERS AND OTHER REGULATORY FLEXIBILITY ENDS (PART 1)

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U.S. Health Care Alert

By: Darlene S. Davis, Rebecca M. Schaefer, Gabriel T. Scott, Cheryl E. Choice

INTRODUCTION

The U.S. Department of Health and Human Services (HHS) and its operating and staff divisions (HHS Divisions) have granted an unprecedented amount of regulatory flexibility to aid health care providers in their response to the COVID-19 pandemic. These flexibilities take the form of (i) waivers or modifications of regulatory requirements issued under Section 1135 of the Social Security Act (the Act) (1135 Waivers), (ii) changes to regulations and policies issued through two Interim Final Rules with Comment Period (IFCs), and (iii) formally articulated enforcement discretion. HHS Divisions have also issued numerous bulletins, guidance documents, FAQs, and fact sheets that provide guidance in regard to new and existing regulations and policies in context of the exigencies of COVID-19. Based on comments by Seema Verma, the administrator for the Centers for Medicare & Medicaid Services (CMS), many in the provider community are hopeful that at least some of these regulatory flexibilities, particularly those related to telehealth, will remain in place after the pandemic subsides.[1] However, the 1135 Waivers and other forms of regulatory flexibility are presently premised on COVID-19 and related emergency authorities discussed herein, and therefore will end at the end of the emergency. This alert describes key considerations in regard to the expiration of various types of regulatory flexibilities and the steps providers can take now to prepare.

BACKGROUND

1135 Waivers

Acting on authority granted by HHS to ensure that sufficient health care services and reimbursement are available in the face of an emergency, CMS has issued numerous blanket 1135 Waivers that are applicable nationally. These 1135 Waivers grant providers a temporary reprieve from compliance with specified requirements, absent any determination of fraud or abuse.[2] The first blanket 1135 Waivers were issued on March 13, 2020, and have been amended and supplemented a number of times, with the most recent release published on May 15, 2020 (collectively, Blanket Waivers).[3] With a retroactive effective date of March 1, 2020, these extensive Blanket Waivers modify or waive requirements related to, *inter alia*, the Physician Self-Referral Law (Stark),[4] telehealth coverage and reimbursement policies, hospital and other provider conditions of participation, and redirection of patients to another location for medical screening under the Emergency Medical Treatment and Labor Act (EMTALA). In addition to Blanket Waivers, CMS has issued individualized waivers to states (including state

Medicaid agencies), health care providers, and health care associations who have made requests on behalf of their respective constituents.[5]

Interim Final Rules With Comment Period

CMS issued in pre-publication form IFCs on March 30, 2020[6] and April 30, 2020[7] to further relax certain regulatory requirements and policies, as well as expand reimbursement available during the COVID-19 public health emergency. A summary of CMS's most recent IFC is available here. Examples of the areas addressed in the IFCs include expanding the circumstances in which care may be delivered and reimbursed as telehealth, relaxing in-person supervision and ordering requirements, addressing the impact of COVID-19 on alternative payment models, providing additional flexibility for temporary expansion of care locations, and loosening specified coverage requirements under certain National and Local Coverage Determinations.

Enforcement Discretion

A variety of HHS Divisions and other federal agencies have announced that they will exercise enforcement discretion in certain areas to ensure that access to care is not inhibited during the public health emergency. As with the focus of the 1135 Waivers and IFCs, enforcement discretion is often focused on rules that would otherwise impede providers' ability to create safe care spaces, preserve access to care, and enable social distancing. For instance, providers are now able to use non-HIPAA compliant technologies, provided they are not public-facing, to provide telehealth services to patients.[8] This policy has allowed numerous providers the ability to quickly adapt to stay-at-home orders without the need to procure specialized technology. Other areas of enforcement discretion allow pathologists to review slides from their homes[9] and certain providers to offer transportation to clinics for patients who have extended courses of treatment, such as chemotherapy.[10]

TIMING FOR TERMINATION OR EXPIRATION OF 1135 WAIVERS, IFC FLEXIBILITIES, AND ENFORCEMENT DISCRETION

The authority of HHS to further authorize CMS to waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements is premised on (1) a national emergency declaration by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act, and (2) a public health emergency (PHE) declaration by the Secretary of HHS (Secretary) pursuant to Section 319 of the Public Health Service Act.[11] The President declared a national emergency due to COVID-19 on March 13, 2020.[12] Prior to the Presidential declaration, Secretary Alex Azar declared a PHE on January 31, 2020.[13] The President's national emergency can be terminated if the President issues a proclamation or if Congress enacts a joint resolution terminating the emergency. A national emergency will automatically expire after one year unless the President renews the proclamation.[14] The Secretary's PHE declaration is effective for the duration of the PHE or 90 days (whichever is earlier), and it may be extended by the Secretary for additional 90-day periods,[15] as has already occurred once for the COVID-19 PHE.[16] Presently, the Secretary's current PHE declaration extends through July 25, 2020.

The Blanket Waivers further provide that waivers under Section 1135 of the Act “typically end no later than the termination of the emergency period, or 60 days from the date the waiver or modification is first published [and] [t]he Secretary can extend the waiver by notice for additional periods of up to 60 days, up to the end of the emergency period.”[17] This reference to a 60-day time frame is based on language in Section 1135 of the Act pertaining to the duration of waivers.[18] The course of CMS's past conduct in regard to PHEs of more than 60

days' duration where CMS had issued 1135 Waivers,[19] language in the waivers issued to states,[20] and CMS's current approach to issuing cumulative Blanket Waivers for the COVID-19 PHE suggest that, so long as the requisite emergency declarations are in place, 1135 Waivers may continue to be relied upon.[21]

The duration of the flexibilities granted through the April and May IFCs is, with certain specified exceptions, expressly tied to the continued existence of the PHE. For purposes of these IFCs, PHE is defined as follows: "the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Security Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals."[22]

As with the 1135 Waivers, the regulatory and policy flexibilities in the April IFC are applicable beginning on March 1, 2020.[23] The May IFC states that the policies described in the rule are applicable beginning on March 1, 2020, or January 27, 2020, except as further described in the rule. Additionally, a few of the changes announced in the IFCs are permanent. These include (1) changes to CMS's ability to grant exceptions to hospitals under the Value-Based Purchasing Program,[25] and (2) permitting physician assistants, nurse practitioners, and clinical nurse specialists to certify and order home health services.[26]

With respect to enforcement discretion, HHS Divisions and other federal agencies have expressed varying time frames for the duration of the regulatory flexibility guidance. A majority indicate that the enforcement discretion will end when the PHE ends. For example, in announcing the HIPAA-related policy noted above, the HHS Office for Civil Rights stated "that it will exercise its enforcement discretion and will waive potential penalties for HIPAA violations against health care providers that serve patients through everyday communications technologies during the COVID-19 nationwide public health emergency."[27] The HHS Office of Inspector General similarly frames flexibility in the application of its administrative enforcement authority on arrangements directly connected to the COVID-19 PHE.[28] To the extent a provider is relying on certain enforcement discretion, such discretion should be evaluated on a case-by-case basis to confirm the specific expiration of that particular compliance protection.

PLANNING FOR THE END OF WAIVERS AND FLEXIBILITIES

While the waivers and flexibilities issued by CMS and other HHS Divisions will end at some point, it is not clear how much notice providers will receive that they are ending or how much latitude there will be to wind down operations that have been conducted in reliance on these waivers and flexibilities.[29] Indeed, as previously noted, language in state Medicaid 1135 Waivers confirms that "[i]n no case will any of these waivers extend past the last day of the public health emergency (or any extension thereof)."[30] As a practical matter, however, the provider community may expect and advocate for some amount of notice from HHS, CMS, and other applicable HHS Divisions to avoid a precipitous overnight end to the regulatory flexibilities that are so critical to providers' ability to safely provide and be reimbursed for care during COVID-19, and which involve complex operational and contractual arrangements that cannot be unwound on a day's notice. If not, uncertainty in this regard would undermine the public policy goals intended by these flexibilities in the first place.

As noted, the number and variety of 1135 Waivers and additional flexibilities under the IFCs and enforcement discretion that have been issued are extensive and impact almost all Medicare provider and supplier types. While we cannot predict when the emergency declarations on which they are premised will end, or if there will be regulatory or statutory changes that will make any of these flexibilities permanent, providers can begin taking

steps now to plan for a post-PHE transition, even while their focus remains on testing and treating COVID-19 patients and re-opening elective service lines.

Cataloguing Waivers

As an initial matter, providers should inventory the waivers and flexibilities that they have implemented or are relying upon, including identifying each provider/supplier within their integrated delivery system that has implemented them, the specific waiver relied upon, and the exact operational or contractual arrangement supported by that waiver. This cataloguing effort could be led by any number of departments or functions within the organization but should include at least the following stakeholders:

- Legal and compliance departments to inform the scope of the inventory, as well as advise on compliance requirements where reliance on a particular regulatory flexibility is identified;
- Clinical service line and other operational leaders, to comprehensively assess where protocols, processes and arrangements have changed in reliance on 1135 Waivers, the IFCs or enforcement discretion;
- Revenue cycle department, including coding and billing personnel, to map the current approaches taken with respect to documentation and claims submission in reliance on COVID-19 regulatory flexibilities; and
- Finance department, to identify additional arrangements that have been impacted or altered in reliance on waivers or other flexibilities, as well as anticipate the challenges with post-PHE transition.

Planning for Unwind

Next, as to each change, the planning documents should identify each of the practical action items that will be required to unwind or transition the arrangement to a compliant non-waiver model. For example, this could include:

- Changes to billing systems and services being provided by telehealth, including planning for the collection of Advance Beneficiary Notices from Medicare beneficiaries where the provision of telehealth does not meet statutory and regulatory requirements;
- Ceasing redirection of patients who present to the emergency department;
- Closing temporary expansion locations or making them permanent to the extent permissible;
- Reinstitution of waived conditions of participation and other payment requirements;
- Discontinuation of arrangements with inpatient rehabilitation facilities, ambulatory surgical centers, and other providers; and
- Implementing HIPAA-compliant telecommunications technologies and entering into business associate agreements with the vendor.

Assessing Other Post-COVID Changes

While this alert is focused on federal waivers and flexibilities, providers will also need to plan for the end of state flexibilities, such as those pertaining to licensure for out-of-state physicians and practitioners and those permitting

temporary increases in licensed bed capacity, and Medicaid waivers. In regard to the latter, to extent such state-level flexibilities are predicated on an 1135 Waiver, they will also end when the 1135 Waiver ends.

CONCLUSION

HHS Divisions have made an unprecedented regulatory response in light of the equally unprecedented scale of the COVID-19 pandemic. The regulatory flexibilities granted through 1135 Waivers, the IFCs, and formally articulated enforcement discretion have been and continue to be instrumental in enabling providers to deliver care safely while maintaining reimbursement. The rollout of these regulatory flexibilities and providers' reliance upon them has been necessarily rapid in order to quickly respond to the COVID-19 public health emergency. However, in light of the temporary nature of these relaxed rules and policies, providers should take steps now to begin to plan for life after the flexibility ends. Such advance planning is important to avoid potential gaps in reimbursement or compliance that may result in overpayments, exposure to audits, and other enforcement risks under the traditional regime, including potential false claims act liability. As providers continue to focus on testing and treating patients, they can also take steps now to track the specific waivers and other flexibilities they are relying upon so that they are prepared when it is time to revert and can mitigate those risks. Overall, developing an adaptable strategy for reverting to prior arrangements, billing procedures, and facility operations will be important for a successful transition after the PHE ends.

K&L Gates LLP has created a HUB webpage to address the legal implications of the COVID-19 outbreak on businesses generally and health care providers, in particular. K&L Gates' health care and FDA practice can provide guidance to providers and suppliers on these and other matters related to the COVID-19 pandemic. Contact the authors of this article or your K&L Gates attorney for assistance or to receive updates during the COVID-19 emergency.

FOOTNOTES

[1] During a press call on April 15, 2020, Seema Verma stated “As we continue to hear from health care providers on the front lines about what's burdensome, it has created a lot of discussion, even within CMS about which, some of these items, do they really need to be continued. We will be assessing this fully after we get past the pandemic” and “We're having those conversations, as well. I think that one example of that that we hear about all the time is telehealth. I think that's a great example of a service that is creating this greater flexibility and accessibility for our patients.”

[2] Social Security Act of § 1135, 42 U.S.C. § 1320b–5 (2018).

[3] Ctrs. for Medicare & Medicaid Servs., COVID-19 EMERGENCY DECLARATION BLANKET WAIVERS FOR HEALTH CARE PROVIDERS (2020).

[4] Ctrs. for Medicare & Medicaid Servs., BLANKET WAIVERS OF SECTION 1877(G) OF THE SOCIAL SECURITY ACT DUE TO DECLARATION OF COVID-19 OUTBREAK IN THE UNITED STATES AS A NATIONAL EMERGENCY (2020). Note, in Part 2 of this series we will explore in depth the considerations related to discontinuing reliance on Stark-related 1135 Waivers for arrangements with physicians.

[5] Ctrs. for Medicare & Medicaid Servs., FEDERAL DISASTER RESOURCES (2020).

[6] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg 19,230 (Apr. 6, 2020) (hereinafter, April IFC).

[7] 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, 85 Fed. Reg. 27,550 (May 8, 2020) (hereinafter, May IFC).

[8] US Dep't of Health & Human Servs., Office for Civil Rights, Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, (Mar. 17, 2020).

[9] Ctrs. for Medicare & Medicaid Servs., LABORATORIES: MEDICARE FLEXIBILITIES TO FIGHT COVID-19 (2020).

[10] U.S. Dep't of Health & Human Servs., Office of Inspector General, FAQS–APPLICATION OF OIG'S ADMINISTRATIVE ENFORCEMENT AUTHORITIES TO ARRANGEMENTS DIRECTLY CONNECTED TO THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY (2020).

[11] Social Security Act of § 1135(g), 42 U.S.C. § 1320b–5(g) (2018).

[12] Donald J. Trump, PROCLAMATION ON DECLARING A NATIONAL EMERGENCY CONCERNING THE NOVEL CORONAVIRUS DISEASE (COVID-19) OUTBREAK (2020).

[13] Alex M. Azar, DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (2020).

[14] 50 U.S.C. § 1622.

[15] U.S. Dep't of Health & Human Servs., PUBLIC HEALTH EMERGENCY DECLARATION (2019).

[16] Alex M. Azar, RENEWAL OF DETERMINATION THAT A PUBLIC HEALTH EMERGENCY EXISTS (effective April 26, 2020).

[17] *Supra* note 3, at 35.

[18] Social Security Act of § 1135(e)(1)(C), (e)(2), 42 U.S.C. § 1320b–5(e)(1)(C), (e)(2) (2018).

[19] Ctrs. for Medicare & Medicaid Servs., HURRICANES & TROPICAL STORMS (Apr. 1, 2020) ("The PHE and 1135 waiver for Typhoon Yutu was extended as of January 22, 2019 (PDF) and expired on April 21, 2019.").

[20] In its explanations of the duration of the Medicaid waivers granted to states, CMS states "Unless otherwise specified above, the section 1135 waivers described herein are effective March 1, 2020 and will terminate upon termination of the public health emergency, including any extensions. In no case will any of these waivers extend past the last day of the public health emergency (or any extension thereof)." *See, e.g.,* Ctrs. for Medicare & Medicaid Servs., SECTION 1135 WAIVER FLEXIBILITIES - NORTH CAROLINA CORONAVIRUS DISEASE 2019 (2020).

[21] Lastly, it is notable that 1135 Waivers may be made effective retroactively to the beginning of the PHE or any subsequent date specified by the Secretary. Accordingly, a technical deficiency, if any, in terms of issuing a formal extension of 1135 Waivers may be easily corrected by the agency. Social Security Act of § 1135(c), 42 U.S.C. § 1320b–5(c) (2018).

[22] 42 C.F.R. § 400.200.

[23] April IFC, 85 Fed. Reg. at 19,230.

[24] May IFC, 85 Fed. Reg. at 27,550, 27,551.

[25] *Supra* note 7, at 5.

[26] *Id*. at 4.

[27] *Supra* note 7.

[28] *Supra* note 10, at n.5.

[29] Interestingly, in regard to the duration of utilization of swing-beds, the Blanket Waiver requires that the hospital implementing swing-beds attest, in part, that it has "a plan to discharge patients as soon as practicable, when a skilled nursing facility (SNF) bed becomes available, or when the PHE ends, whichever is earlier." *Supra* note 3, at 8. This does suggest some understanding that it may not be possible to immediately discharge a patient receiving SNF-level care in a swing-bed after the PHE ends.

[30] *Supra* note 20.

KEY CONTACTS

DARLENE S. DAVIS
PARTNER

RESEARCH TRIANGLE PARK
+1.919.466.1119
DARLENE.DAVIS@KLGATES.COM

REBECCA M. SCHAEFER
PARTNER

RESEARCH TRIANGLE PARK
+1.919.466.1111
REBECCA.SCHAEFER@KLGATES.COM

GABRIEL T. SCOTT
PARTNER

RESEARCH TRIANGLE PARK
+1.919.466.1263
GABRIEL.SCOTT@KLGATES.COM

