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KEY THEMES

- Alternative payment models offered by the Center for Medicare and Medicaid Innovation (CMMI) often include multiple waivers, which are intended as incentives to encourage participation and to help participating organizations succeed under the model. The waivers can give model participants greater flexibility in care delivery, allow them to offer new benefits and patient incentives, and let them collaborate in new ways with other delivery organizations.
- However, waiver adoption remains modest; in one model only 8 percent of participants used a telehealth waiver and 4 percent leveraged a waiver allowing for faster discharge from a hospital to a skilled nursing facility.
- Providers identify multiple reasons why they may not take advantage of the waivers in their CMMI alternative payment model, such as concerns about compliance, difficulty identifying beneficiaries eligible for the waiver, the administrative burden to meet waiver requirements, and resource constraints or competing priorities that limit their ability to implement new care approaches. Moreover, waivers available during the COVID-19 public health emergency (like for telehealth) may be more expansive and automatic than the alternative payment models' versions, reducing the attractiveness and payoff of normal waivers.
- Waivers can be improved by expanding technical guidance and increasing clarity about what is allowed in implementing waivers; reducing the administrative complexity involved, such as in the waiver application; and aligning waivers, such as through a core set of waivers across CMMI-sponsored models.

Introduction

Over the last decade, the Centers for Medicare and Medicaid Services (CMS) has encouraged health providers to transition to new alternative payment models (APMs) aimed at delivering better care at lower cost. To encourage providers to participate and succeed in these APMs, CMS introduced waivers to federal regulations around care delivery models, patient incentives and benefits, and coordination between care delivery organizations (see Box). However, despite the potential benefits afforded by waivers, adoption remains limited.

This brief considers how waiver flexibilities are currently being used, how they can be improved, and how some of the flexibilities introduced during COVID-19 can be maintained and used more effectively in advanced payment reforms after the pandemic. This brief considers waivers specific to APMs in the Center for Medicare and Medicaid Innovation (CMMI), given CMMI's regulatory authority to more easily and quickly design and change waivers, although the challenges are often similar in other CMS APMs. This brief also draws on interviews with organizations overseeing or participating in alternative payment models, interviews with other health policy experts, and reviews of evaluations and published research about APMs.

WHY DO WAIVERS EXIST?

Waivers allow APM providers to undertake certain activities that can improve care but otherwise would be prohibited by federal law.

Congress and other federal agencies enacted a variety of laws and regulations designed to prevent inappropriate provider behavior under fee-for-service payments.

Key laws and associated regulations include:

- The Anti-Kickback Statute (AKS), which prohibits individuals from receiving or giving payments or anything of value to incentivize or reward referrals for treatment paid by federal health care programs like Medicare and Medicaid;¹
- The Physician Self-Referral Law (also known as Stark Law), which prevents physicians from referring Medicare patients to receive certain health services to an entity with whom the physician has a financial relationship;² and
- The Civil Monetary Penalty (CMP) beneficiary inducement provisions, which prevent providers from paying Medicare beneficiaries “to influence the beneficiary’s decision to receive services from a particular provider, practitioner, or supplier.”³

However, these laws can unintentionally create obstacles to care transformation efforts that seek to improve the quality and efficiency of how care is delivered. For example, physicians and other providers are normally limited in their ability to share financial savings for reducing costs, provide financial incentives to encourage beneficiaries to seek care, or help steer patients to higher quality providers without facing regulatory scrutiny and potentially financial or criminal penalties. These restrictions may not be needed outside of the fee-for-service context in APMs where providers are accountable for total cost of care and care quality.

How Are Waivers Used Now in Alternative Payment Models?

Waivers commonly fall into three categories: care delivery design, patient engagement incentives and benefits, and participant coordination waivers. Table 1 illustrates how the above waiver categories are applied in practice, including specific waiver examples and examples of programs offering these types of waivers. The waivers allow for the following flexibilities for providers:

- **Care Delivery Design** – waivers of certain Medicare payment rules for the purpose of testing strategies for delivering and managing care across providers. Examples include allowing coverage of skilled nursing facility (SNF) admissions without a qualifying three-day hospital stay or allowing clinicians to provide home visits after a patient is discharged from the hospital.
- **Patient Engagement Incentives and Benefits** (also referred to as beneficiary inducements) – waivers that enable providers to offer incentives

(monetary and non-monetary) that encourage usage of preventative care, treatment or drug regimen adherence, or management of chronic disease. Examples include prepaid vouchers for transportation services, coupons or rebates for retailer reward programs, or payments to reduce or eliminate patient cost-sharing (e.g., copayments, coinsurance, and deductibles) for certain Medicare Part B services.

- **Participant Coordination** – waivers that permit the structural and financial arrangements necessary for providers to form and operate as program participants in CMS- and CMMI-sponsored models. For instance, the payment waiver in the Comprehensive Care for Joint Replacement (CJR) Model allows providers to distribute realized savings across providers.

As participant coordination waivers are a fundamental feature of CMS and CMMI-sponsored models, this brief primarily focuses on waivers related to care delivery design and patient engagement incentives.

TABLE 1

Examples of Waivers

Type	Waiver Examples	Description	Example Program
Care Delivery Design	3-Day SNF	Allows for patient to be admitted to a SNF without a prior 3-day hospital stay	NGACO ⁵ DC ⁶
	Post-Discharge Home-Visit	Allows for a limited number of home visits after discharge from an inpatient facility	NGACOs ⁷ BPCI-A ⁸ DC ⁶
	Care Management Home Visits	Allows a home visit by a clinician (or auxiliary personnel under clinician supervision) in advance of a potential hospitalization	NGACO ⁷ DC ⁶
Patient Engagement Incentives and Benefits	Cost Sharing	Reduces cost sharing amounts for certain Medicare Part B services to minimize beneficiary financial barriers	NGACO ⁹ PCF ¹⁰
	Chronic Disease Management Reward	Permits up to \$75 worth of gift card(s) per year to encourage eligible beneficiaries to participate in chronic disease management programs	NGACO ⁹ DC ⁶
	Chronic Disease Management Reward	Permits certain providers to offer in-kind (free) items or services that are reasonably related to the program purpose and promote patient engagement or management of care, such as an at-home health monitoring device.	CJR ⁴ CEC ¹¹
Participant Coordination	Pre-Participation Waivers	Protects organizations in anticipation of participating in an APM program. For instance, the Implementation Period Participation Agreement in Direct Contracting “protects certain startup arrangements... in preparation for participation in the performance period.” ¹²	DC ¹² NGACO ⁹
	Participation Waiver	Waives portions of the Federal anti-kickback statute and the physician self-referral law to enable participants to undertake certain activities that “promote accountability for the quality, cost, and overall care” for the model beneficiaries like infrastructure investment or redesigned care processes— while still maintaining pieces of the statute that appropriately prohibit fraud and abuse.	NGACO ⁹ DC ¹²
	Payment Related Waivers	Allows for payment arrangements across participants fundamentally necessary for program participation that would normally be prohibited. For instance, sharing program savings (gainsharing) across participating providers.	NGACO ⁹ BPCI-A ¹³ CEC ¹¹ CJR ⁴ OCM ¹⁴

Notes: BPCI-A = Bundled Payments for Care Improvement Advanced Model, CEC= Comprehensive End-Stage Renal Disease Care Model, CJR = Comprehensive Care for Joint Replacement Model, DC = Global and Professional Options of the Direct Contracting Model, NGACO = Next Generation Accountable Care Organization Model, OCM= Oncology Care Model, PCF = Primary Care First Model

Waiver adoption remains modest. While waivers have been designed to encourage participation and have substantial potential for care redesign and patient engagement, studies have found that many waivers are infrequently used. For instance, a 2020 study of the Next Generation Accountable Care Organizations (NGACO) model found only 12 percent of ACOs in the model used the post-discharge home visit waivers and 8 percent used the telehealth waiver. Further, while the SNF 3-day waiver was the most common waiver utilized by ACOs in the model, only approximately 4 percent of SNF stays were attributed to the SNF 3-Day waiver.¹⁵ Similar waiver participation rates were found for the Bundled Payments for Care Improvement model (BPCI)—2% used the post-discharge home visit, 37% used some type of patient engagement incentive, and 37% used gainsharing waivers to distribute savings to their partners.¹⁶ These trends have also occurred in non-CMMI APMs like the Medicare Shared Savings Program.¹⁷ Qualitative interviews with providers, policymakers, and industry experts conducted for this brief confirmed the above findings; despite widespread interest, most organizations did not elect to implement waivers.

An additional challenge to the appeal of typical CMMI waivers arose in 2020 related to the COVID-19 pandemic as the Department of Health and Human Services (HHS) temporarily issued blanket waivers during the public health emergency. For example, HHS provided greater flexibility for all clinicians to use telehealth (including audio-only) for their Medicare patients, regardless of whether they were in an APM or not. In interviews, several clinicians noted that these COVID-related waivers were often more expansive than their existing APM-related waivers, which reduced the attractiveness and cost-benefit profile of APM waivers during the public health emergency.

KEY TAKEAWAYS

Waivers were designed to provide regulatory flexibilities for program participants to collaborate, innovate, and redesign care in ways that may be problematic under fee-for-service payments (and therefore are prohibited under existing federal law). Despite these benefits, widespread adoption of all types of waivers remains limited.

Waivers Usage: Challenges, Solutions, and Recommendations

Although organizations we interviewed appreciated the intent behind waivers and the opportunity they provide, they noted that investment costs and potential legal risks associated with implementing waivers outweigh financial returns or improvements in clinical outcomes. Common factors that stymie wider adoption include concerns around risk compliance, administrative and logistical burdens, a limited pool of beneficiaries that qualify for the waiver, and inconsistency in how waivers are applied across models. Organizations that have had success in waiver implementation typically have prior experience in value-based payment models, where they have had sufficient time to develop the resources and infrastructure needed to maximize waiver benefits.

Below we summarize key themes from our interviews on the challenges and opportunities organizations participating in APMs face around waivers. We offer recommendations in each section to strengthen waiver design and encourage wider adoption.

Compliance Uncertainty

Further clarity needed on waiver scope and legal risks. Participants emphasized that they are hesitant to implement several waivers due to liability concerns. This is particularly challenging for smaller organizations that lack extensive legal resources or in-house compliance teams to assess legal protection.¹⁸

Stakeholders we interviewed reported confusion as to whether they are correctly interpreting and meeting

waiver compliance requirements, particularly since waiver provisions can be ambiguous. Waivers require that the activities or arrangements be reasonably related to the purposes of the program, which some have noted is a vague and broad standard.¹⁹ As an example, while it may be patently and obviously inappropriate to use patient engagement waivers for transporting beneficiaries to entertainment events unrelated to care,⁹ it is less clear whether the waiver would apply to other more common examples, such as for transportation services for medical appointments during which the beneficiary also makes an additional stop to pick up food.

Organizations are also uncertain what legal sanctions they could face if they unintentionally violate waiver provisions. One stakeholder summarized: “There is zero case law on what happens if you implement a waiver under a CMS value-based program and CMS determines that you were not within the bounds of the waiver. Nobody knows if they’re going to get a slap on the wrist and have CMS say stop doing that or if they’re going to jail for 15 years. It’s a very broad spectrum. Are they going to pay a small fine? Huge fine? [Are they] excluded from providing all health care services in the future?” To mitigate compliance concerns, one stakeholder comprehensively documented all communication with CMS to demonstrate they “have good intentions and are not trying to work around the model.”

Several stakeholders also mentioned difficulty adhering to frequently changing deadlines or reporting requirements without advance notice of changes. As an example, one organization noted that they are participating in the Direct Contracting program, but did not know dates for submitting materials several months before the key application materials are typically needed, which makes it difficult to plan ahead. As a result, the organization noted they are having to make decisions in a limited time period without knowing full participation details.

Moreover, participants would like CMS to provide explicit confirmation of the waiver application compliance status. Stakeholders noted that CMS will notify participants if a waiver application is not compliant but does not notify participants if a waiver application is compliant. Instead, participants are often advised to consult with their legal team to ensure that “arrangements for which they seek waiver protection meet all required conditions.”²⁰

Organizations recognize that CMS and OIG make continual effort to provide a range of resources, tools, and support mechanisms to address all the information gaps they can. CMS and CMMI offer programmatic information, frequently asked questions (FAQs), and other documents that further explain what activities are afforded waiver protection. Over time, the information provided in these documents has increased to further address existing information gaps. Platforms like the Medicare Learning Network offer trainings and other educational materials for participants. CMS has also provided matchmaking services to pair high and low waiver utilizers to discuss strategies and barriers; individual coaching calls with participants and subject matter experts; and toolkits and case studies highlighting best practices and strategies for waiver implementation. However, participants indicated that these resources are often not applicable to their specific circumstance and unique population needs. Additionally, though the HHS Office of the Inspector General (OIG) issues advisory opinions on fraud and abuse laws,²¹ these are case-specific and not generalizable.

Yet CMS and CMMI are limited in what legal and regulatory information they can offer. Internal protocols and legal constraints hamper the ability of CMS and CMMI to provide the above guidance. For example, CMS notes they “cannot comment on individual circumstances”²² and must work within existing public documents and statements. Despite these constraints in what advice they can offer, interviewed stakeholders noted that CMMI officials have been receptive to feedback.

Recommendations

Increase guidance where possible. OIG, CMS, CMMI, and other relevant agencies should consider opportunities to coordinate federal communication around waiver authorities and explore additional ways for participants to solicit feedback and address compliance concerns. One option would be for OIG and CMS to collaborate in managing the legal, regulatory, and operational constraints of offering guidance specific to individual waiver applicant circumstances, such as additional guidance for common situations (building on CMS’ recently expanded FAQs), forums where waiver applicants can ask questions, or other individualized feedback.

Federal agencies should also consider opportunities to provide additional technical assistance in accordance with the parameters set by institutional practices and federal regulations. As an example, CMS and CMMI could provide additional case studies of how waivers may be utilized with examples of activities that are not compliant with existing waivers. Additionally, CMS and CMMI should assess strategies to notify participants of their waiver application status, such as whether their waiver application would meet compliance requirements if implemented as described, in order to reassure participants of compliance concerns.

Support additional venues for participants to exchange strategies. Stakeholders indicated they were less candid in formal CMMI-sponsored learning groups because they have a political relationship to maintain with CMMI and CMS. This led to “sanitized” conversations and recommendations. CMS may consider ways to address this concern and support a neutral convening forum that fosters an environment in which participants feel they can speak more candidly.

More safe harbors for when waivers are incorrectly applied. CMS should consider strategies to offer additional safe harbors for unintentional waiver usage. CMS and other relevant teams should consider additional activities that could be afforded safe harbor protection, such as if a model participant implements a waiver in good faith but inadvertently does not meet the waiver’s regulatory or legal standards. (Similar to waivers, safe harbor regulations are legal provisions that permit certain practices that would otherwise implicate fraud and abuse statutes. Unlike waivers, which must be issued and approved, safe harbor models afford protection without requiring model participants to apply for separate waivers.) Another option would be for CMS to allow for a limited number of annual exemptions for payments rendered to ineligible patients.

KEY TAKEAWAYS

- Participants do not fully understand what activities are protected by waivers and what repercussions they may face if they provide services outside of a waiver’s authority.
- Although CMS and CMMI are limited in what formal legal guidance they can provide on individual circumstances, they should provide additional technical assistance, guidance, and feedback to help reassure organizations and clarify compliance risks.
- OIG and CMS should collaborate in managing the legal, regulatory, and operational constraints of offering guidance specific to individual waiver applicant circumstances, such as additional guidance for common situations, forums where waiver applicants can ask questions, or other individualized feedback.

Waiver Alignment

Variation in waiver benefits creates additional complexity and confusion for model participants.

While waiver benefits are often similar across models, design features can vary depending on the model. For instance, providers in Medicare Shared Savings Program can provide \$20 to beneficiaries for certain primary care services while providers in CMMI’s Next Generation ACO model can provide up to \$25 to beneficiaries who received an annual wellness visit (though this waiver

has now been discontinued).²³ Inconsistent waiver design is cumbersome for model participants, requiring additional organizational resources and dedicated staff time to ensure compliance.

Variation in waiver application processes. Each waiver application also requires a separate application process, increasing the workload for model participants and federal health teams. For instance, a participant must submit applications for each waiver they elect to participate in. Many of these waivers tackle similar

issues, and organizations emphasized that there is opportunity to standardize applications across common waiver archetypes.

Variation in waiver development and approval processes. No single federal entity is responsible for administering and regulating waivers. Waivers can be issued jointly or separately by CMMI and OIG (e.g., OIG solely issues Primary Care First waivers).²⁰ Furthermore, multiple divisions within CMMI are responsible for coordination to support the development and implementation of models.²⁴ Teams must also coordinate to ensure that Medicare billing claims continue to be processed reliably and correctly. Examples include technical modifications (e.g., creating or modifying billing codes to process claims) and ensuring that Medicare Administrative Contractors (third party contractors responsible for administering and processing Medicare Part A and B claims) can appropriately process and validate waiver inquiries. As a result, the authority to develop, approve, and oversee waivers is complex, requiring coordination across different CMS and HHS teams.

Waivers must also go through a legal review process on an individual basis (e.g., ensuring that waiver requirements are satisfied). For instance, federal regulations stipulate that waivers must be determined “as necessary” to carry out model demonstrations. To make this determination, CMMI consults with the Office of General Counsel (OGC), OIG, and Center for Medicare’s Division of Technical Payment Policy. The result is a lengthy process, requiring significant advanced planning.

Recommendations

Streamline waivers across programs to allow providers to use flexibilities afforded by CMS across APM models. One approach to align waivers is for CMS to develop a core set of standard waivers across value-based payment programs. As an example, CMS and CMMI could develop a customizable template applicable to all waivers of a particular waiver type across different APM programs. For example, referring back to the major waiver types in Table 1, CMS could harmonize the application process for all care delivery waiver types via one template, and then similarly for all benefit enhancement waivers via another template.

Another approach is to provide default flexibilities for participants in downside risk arrangements. Under this strategy, participants meeting or exceeding a threshold of revenue in downside risk would, by default, be eligible

for a set of standard waivers, instead of going through an application process. This approach mirrors recent action taken by CMS and OIG (detailed further below) that afford greater flexibilities “for arrangements where the parties assumed more financial risk.”²⁵ (However, CMS should monitor the degree to which predicating certain waivers on higher levels of risk could dissuade organizations not ready for significant financial risk from joining the program – a concern expressed by the National Association of ACOs.²⁶) This eliminates the current “opt-in” approach, which, as others have noted,²⁷ would reduce administrative complexity for both CMS and model participants. In some instances, this may require legislative changes, as CMS may not have sufficient existing authority to make this type of change.

CMS should also work with model participants to improve evaluation of waiver success. To do so, CMS should differentiate waivers that can improve care coordination from waivers that may be financially rewarding for model participants but do not lead to tangible improvements in care delivery. However, CMMI and CMS are limited in their ability to evaluate individual waiver effects. Some interviewees noted that federal agencies lack specific information on how certain waivers are being utilized. Additional data collection methods could help inform CMS and CMMI efforts to improve waiver design and waiver evaluations. CMMI and CMS should coordinate with model participants and model evaluators to improve visibility into waiver usage in a manner least burdensome to participants.

HHS, CMS, OIG and other regulatory bodies should continue to build off recent initiatives intended to align waivers and reduce administrative burden.

In 2018, HHS announced the “Regulatory Sprint to Coordinated Care”, an effort to reduce regulatory barriers that may impede efforts to improve care coordination and transition to value-based care. As part of this effort, OIG and CMS modified federal regulations in 2020 to provide greater predictability and uniformity across models.^{25,27} For instance, OIG codified some existing waivers and expanded safe harbor options. Codifying waivers can, as others have noted, provide program stability and mitigate provider concerns that waivers may be revoked or changed.²⁸ Expanded safe harbors in the final rule can also eliminate the need for individual model-specific fraud and abuse waivers.²⁵ CMS and OIG should continue to build off these activities by identifying pathways for participation that impose fewer requirements.

To reduce administrative burden, interviewed organizations also cited several strategies to improving waivers, like broadening the number of health professionals that can evaluate and approve beneficiaries for SNF admission

(under a SNF 3-day waiver), eliminating geographic restrictions in telehealth services, or offering an extended grace period for organizations that exceed the Annual Wellness Visit limit.

KEY TAKEAWAYS

Waiver design varies across models, creating additional administrative challenges for organizations. Aligning waivers, whether by creating uniform waiver benefits across models or streamlining the waiver application process, could help reduce this administrative complexity for both participants and CMS and CMMI.

Resource Constraints

Implementing waivers can be administratively burdensome and time-intensive. In order to realize a waiver's benefits, participating organizations typically need to make significant changes to how they deliver care.

Many waivers require significant changes to an organization's data and technology infrastructure. For instance, to ensure a beneficiary is eligible for the 3-Day SNF waiver, health systems need the ability to share admission and discharge information and other care-planning details with participant SNFs, frontline clinicians, and care managers while also ensuring that software challenges do not impede timely transmission to the SNF facility. This requires IT modifications, like real-time data collection to inform care-deliver decisions, data exchange capabilities across participating providers, or electronic health record (EHR)-embedded alerts to help staff identify and confirm beneficiary eligibility.

Care delivery organizations often have to redesign clinical workflows for waiver eligible patients. Some waivers require significant clinical changes, like embedding care managers in the emergency department to assist with discharge and transfers. These waivers may also require significant administrative support to ensure compliance, which may require establishing dedicated care teams responsible for optimizing care coordination and adhering to waiver criteria. If the number of patients served by the waiver is small or the return on investment (in terms of care improvements or finances) is small, the care delivery organization may choose to remain with the status quo rather than implementing the waiver.

Many organizations lack the resources to take advantage of waivers. Several interviewed organizations noted those groups more likely to implement waivers tended to be larger, had more resources, or had existing infrastructure that could be repurposed for the waiver. Others noted that while size may facilitate waiver adoption, organizational structure can be a greater determinant of success. A small ACO that consists of a single legal organization with a centralized operating infrastructure can be nimbler than a decentralized group of independent providers—though the small ACO may not have the cash resources or infrastructure to make the necessary changes without significant financial strain.¹⁸ A large group of loosely affiliated practices may encounter distinct workflows, cultures, and billing arrangements that can be more challenging to navigate than a tightly integrated system.

As a result, many organizations apply for waivers but do not follow through with implementation. Interviewed stakeholders indicated that they often stall with administering waivers because the heavy lifting is front-loaded, requiring significant upfront resources, staff time, and infrastructure modification. These changes often occur as organizations are also entering their first performance year and other care delivery tasks take priority since “there are always operational things that need to get done.” As a result, waivers often get stuck after the application stage. To address these challenges, some organizations hired outside consultants to help with data analytics capabilities, forecasting waiver impact, and utilization patterns. Some stakeholders took a phased approach to implementation, piloting waivers with a small group of providers and

then gradually expanding over time. Others were more cautious, waiting to learn from the experiences of early waiver adopters before moving forward.

“Our resources are limited so it’s very important for us to know if the juice is worth the squeeze. There is a lot of data gathering, a lot of administrative costs, a lot of time involved and we have to weigh that against what we are going to get out of the program.”

Limited benefits.

Some stakeholders felt that waivers did not apply to a large enough patient population or provide a sufficient return on investment to warrant adoption. For instance, some organizations noted that restrictions on the visits allowed

under the post-discharge follow-up home visit waiver can make it “not worth the investment”¹⁵ for a care delivery organization and gainsharing caps in BPCI may make “it difficult to engage partners and motivate behavior change.”¹⁶ Some stakeholder indicated that patient engagement incentives are insufficient to meaningfully change patient behavior. Others noted that the available pool of patients eligible for a waiver is too small. Organizations struggle to identify eligible patients (discussed further below) and policy restrictions can limit the number of beneficiaries eligible. For instance, NGACO beneficiaries with Medigap are ineligible to receive cost sharing support.²⁹

In some circumstances, CMMI and CMS sponsored models may afford flexibilities that do not require waiver protection. For instance, some NGACOs choose not to use the post-discharge follow-up home visit waiver because they could provide care management services telephonically and conduct home visits without the waiver.¹⁵

Recommendations

Review opportunities to reduce administrative burden. CMS and CMMI teams should work with participants to identify ways to simplify reporting requirements without affecting program evaluation efforts. CMS and CMMI teams should coordinate to provide advance notice of changes in reporting requirements to reduce uncertainty during the application process.

Expand population eligible for waivers. Participating organizations have unique patient population needs, yet waivers are designed for specific situations. CMS and CMMI teams should engage model participants to broaden waivers. Several stakeholders noted that existing waivers are too prescriptive and narrow and suggested CMS and CMMI adopt an approach in which they provide basic guidance around what activities might be acceptable and approve implementation plans that fall within this guidance. Participants would have greater creativity in designing waivers without having to “fit the needs of their specific population into very prescriptive benefit enhancements and waivers.”

Provide additional upfront resources. CMS should consider mechanisms to provide upfront support (e.g., loans from future shared savings like the ACO Investment Model) to help organizations build up the infrastructure for waiver implementation and administering beneficiary incentives.

KEY TAKEAWAYS

- Implementing waivers can be time and resource intensive, requiring upfront capital, dedicated staff time, and infrastructure modifications.
- For some organizations, waivers offer limited additional value to justify the investments needed to use waivers.
- CMS, CMMI, and other federal agencies should consider ways to reduce the administrative burden and provide greater flexibility for how waivers can be administered.

Identifying and Communicating with Patients

Challenges identifying eligible patients. Across models, interviewees cited the difficulties identifying patients that qualify for the waivers. Stringent criteria around patient eligibility contributes to the problem. For example, for the SNF 3-day waiver, patients must meet all of the following criteria:

- Not reside in a SNF or other long-term care setting;
- Be medically stable;
- Not require inpatient or further inpatient hospital evaluation or treatment;
- Have certain confirmed diagnoses;
- Have an identified skilled nursing or rehabilitation need that they cannot receive as an outpatient; and
- Have been evaluated and approved for admission to the SNF within 3 days prior to the SNF admission by an ACO provider/supplier that is a physician, consistent with the ACO's beneficiary evaluation and admission plan.³⁰

While these stipulations may be necessary to ensure the right services are delivered to the right patient, organizations noted this can impede waiver usage because of the need to prove each specific criterion. These criteria often require challenging data analysis that may be open to interpretation. Further, organizations may have a limited window of time in the SNF 3-day waiver to identify patients. Organizations we interviewed were concerned that, despite their honest and best effort, they may accidentally apply waiver benefits to ineligible patients, which could result in financial costs or other liabilities. For example, if a patient is transferred directly to a SNF facility and it is later determined they did not qualify for the waiver, CMS can deny payments for the SNF stay, leading the SNF to seek to recoup payments from the provider or beneficiary. Several ACOs in the NextGen ACO program noted they paused or discontinued use of the SNF waiver over frustration with authorization challenges, multiple denials, abuse of SNF services, and lack of a control mechanism.¹⁵

Difficult to train and educate staff about waiver qualifications and process. Because waivers are often triggered at the patient-provider encounter, frontline clinicians and staff play a critical role ensuring waivers are used appropriately and to their full potential. However, interviewees reported practical implementation challenges, including increasing provider work burden. Despite holding informational sessions training providers on waiver criteria, stakeholders could not find effective ways to ensure the eligibility criteria was “top of mind” during patient encounters. One organization noted that during the performance year, only one beneficiary was eligible for the SNF 3-day waiver. “When you start a program a bunch of people say ‘I wish we had this program last week.... I had three patients that would have qualified’ and then once you start the program these patients kind of disappear through the woodwork. It’s very frustrating.”

As with any change, care delivery organizations must gain provider buy-in for new care workflows and educate and train staff about new processes. For example, one health system noted that they found low uptake of the SNF 3-day waiver because their physicians are accustomed to the 3-Day SNF rule and “don’t want to deal with the headache” of the waiver and find it is “just easier to admit the patient.”

Communicating waiver criteria to patients and providers is part of the challenge. ACOs and other alternative model program participants highlighted the challenges around explaining value-based payment models to beneficiaries. They noted that it is even more challenging to explain participation in a *waiver or benefit enhancement* as part of a new value-based model program. Policies impacting beneficiary eligibility are complex and can easily be misconstrued. For instance, NGACO beneficiaries are ineligible for cost sharing waivers if they have Medigap coverage. Conveying this health policy technicality to providers and patients is cumbersome, particularly when time is limited during clinical encounters.

CMS has provided guidance to help organizations communicate effectively with patients and dispel confusion.³¹ However, interviewees noted that challenges remain. For instance, several interviewees reported that patients believed the chronic disease gift card was a scam. Older adults may also be more skeptical of unfamiliar incentives since they are often the targets

of scams.³² Additionally, stakeholders highlighted that stringent communication requirements can further confuse beneficiaries. For instance, beneficiary notification letters list CMS' "1-800-MEDICARE" number but, according to interviewees, CMS representatives cannot answer specific questions related to the participant organization.

Recommendations

We identified several existing tools and tips—and generated new lessons from interviews—regarding better identification of patients for APM waivers and benefit programs. In terms of organizational structure, multiple ACOs recommended having a centralized, proactive identification team analyze the data³⁴ and a “gatekeeper” staff member overseeing waiver eligibility instead of identifying eligible patients in decentralized settings.¹⁵ CMS has also developed tools to help identify patients in real time. For example, the ACO User Interface (ACO-UI) enables NGACOs to confirm beneficiary and SNF eligibility for using the SNF 3-Day waiver, though the tool is limited to the NGACO model and seems to be underutilized.⁵ One ACO noted that having the same EHR across ACO care agencies and clinics helped with consistent identification, although this can be challenging for small, physician-led ACOs that often have different EHR systems.³³ Other interviewed organizations invested in training auxiliary personnel to assist in identifying patient eligibility or implemented an EHR notification to automatically flag patient eligibility at the clinical encounter. Organizations also noted that prospectively assigned beneficiaries allows providers to identify eligible patients more easily and can reduce the administrative burden required to keep track of patients.³⁴

Provide tools and guidance on how to identify eligible patients. In our interviews, stakeholders emphasized that there is opportunity for additional tools, educational assistance, and infrastructure support to better identify patients. As we noted above, providers often are unaware of patient eligibility at the time of a clinical encounter. Others also highlighted the need to provide guidance to assist providers in identifying patient eligibility, particularly for staff not affiliated with the model participant.¹⁵

Ensure patient communication is clear. One suggestion from our interviews was to simply allow the communication to list a contact number for the local participant organization so that they can speak to the clinical group they know and trust. Extending that concept, CMS could consider allowing other ways for local participating organizations and their provider groups to customize their communications, such as using local letterhead or providing a customized message about the group.

KEY TAKEAWAYS

- Identifying patients that are eligible for waivers is difficult. In many instances, only a small number of patients qualify for waivers, limiting the utility of waivers. The criteria determining beneficiary eligibility is also complex and difficult to explain to providers and patients, leading to confusion or missed opportunities.
- Organizations welcome additional resources to better identify patients proactively and flexibility to communicate with patients more effectively.

Conclusion

Waivers were designed to encourage participation in alternative payment models and drive beneficial care delivery transformations. By affording organizations regulatory relief from certain federal laws, waivers can promote value-based arrangements by reducing obstacles to delivering high-quality, integrated care. These regulatory flexibilities enable organizations to deliver care across providers in innovative ways, offer incentives to beneficiaries to encourage health-promoting activities, and develop financial arrangements that align providers around quality and efficiency improvements.

As our research has made clear, many organizations have not elected to utilize waivers despite the flexibilities offered. There is a frequent concern that the investment costs, administrative burden, and perceived legal risks associated with implementing waivers outweigh any potential financial or clinical benefits. Federal agencies can help address these concerns through a variety of actions, including broadening the use of these waivers where appropriate, clarifying the scope of waivers, and streamlining waiver design and reporting requirements across models. These modifications can strengthen waivers and support CMS' continued effort to advance value-based payment systems.

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References

- ¹ Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)–(2).
- ² Centers for Medicare and Medicaid Services. Physician Self Referral. Updated March 16, 2021. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral>
- ³ Civil Monetary Penalties. 42 U.S.C. § 1320a-7a(a)(5) (2012).
- ⁴ Centers for Medicare and Medicaid Services. Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive Care for Joint Replacement Model. January 1, 2018. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2017-CJR-Model-Waivers.pdf>
- ⁵ The Center for Medicare and Medicaid Innovation. Next Generation ACO Model Skilled Nursing Facility (SNF) Three-Day Rule Waiver. May 2021. Available at: <https://innovation.cms.gov/files/x/pioneeraco-snfwaiver.pdf>
- ⁶ The Center for Medicare and Medicaid Innovation. Direct Contracting (Professional and Global) Frequently Asked Questions. October 2020. Available at: <https://innovation.cms.gov/files/x/dc-faqs.pdf>
- ⁷ The Center for Medicare and Medicaid Innovation. Next Generation ACO Model Post-discharge and Care Management Home Visit Waivers. May 2021. Available at: <https://innovation.cms.gov/files/x/nextgenaco-pd-caremgmt-homevisit-waivers.pdf>
- ⁸ The Center for Medicare and Medicaid Innovation. Bundled Payments for Care Improvement Advanced Participation Agreement. August 1, 2018. Available at: <https://innovation.cms.gov/files/x/bpciadvanced-participation-agreement.pdf>
- ⁹ Centers for Medicare and Medicaid Services. Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection with the Next Generation ACO Model. December 12, 2018. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/next-gen-aco-2nd-amended-waivers-12122018.pdf>
- ¹⁰ Centers for Medicare and Medicaid Services. Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Primary Care First Component of the Primary Care First Model. December 16, 2020. Available at: <https://www.cms.gov/files/document/notice-waiver-certain-fraud-and-abuse-laws-connection-primary-care-first-component-primary-care.pdf>
- ¹¹ Centers for Medicare and Medicaid Services. Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Comprehensive ESRD Care Initiative Non-LDO Model. July 15, 2015. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/CEC-Non-LDO-Model-Waivers.pdf>
- ¹² Centers for Medicare and Medicaid Services. Notice of Waiver of Certain Fraud and Abuse Laws in Connection With the Global and Professional Options of the Direct Contracting Model. September 18, 2020. Available at: <https://www.cms.gov/files/document/notice-waiver-certain-fraud-and-abuse-laws-connection-global-and-professional-options-direct.pdf>
- ¹³ Centers for Medicare and Medicaid Services. Notice of Amended Waivers of Certain Fraud and Abuse Laws in Connection With the Bundled Payments for Care Improvement Advanced Model. January 1, 2020. Available at: <https://www.cms.gov/files/document/notice-amended-waivers-certain-fraud-and-abuse-laws-connection-bundled-payments-care-improvement.pdf>
- ¹⁴ Centers for Medicare and Medicaid Services. Notice of Waivers of Certain Fraud and Abuse Laws in Connection with the Oncology Care Model. April 28, 2016. Available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/OCM-Waiver.pdf>
- ¹⁵ NORC at the University of Chicago. Third evaluation report: Next Generation Accountable Care Organization Model evaluation. Report prepared by staff from NORC at the University of Chicago for the Center for Medicare & Medicaid Innovation. September 2020. Available at: <https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport>
- ¹⁶ The Lewin Group. CMS Bundled Payments for Care Improvement Initiative Models 24: Year 5 Evaluation & Monitoring Annual Report. October 2018. Available at: <https://downloads.cms.gov/files/cmimi/bpci-models2-4-yr5evalrpt.pdf>
- ¹⁷ Buck C, Healy P, McDermott W. “Medicare ACO Participation Waiver of Fraud and Abuse Laws: How It Works and Why ACOs Should Use It.” Health Law Connections. December, 2014. Available at: https://s3-us-east-2.amazonaws.com/mwe.media/wp-content/uploads/2019/04/05160917/ahla_connections_1214.pdf
- ¹⁸ Gonzalez-Smith J, Crook H, Singletary E, Bleser W, Saunders R. How to Better Support Small Physician-led Accountable Care Organizations: Recent Program Updates, Challenges, and Policy Implications. February 2020. Available at: <https://healthpolicy.duke.edu/sites/default/files/2020-07/How%20to%20Better%20Support%20Small%20Physician-Led%20ACOs.pdf>
- ¹⁹ Centers for Medicare and Medicaid Services. Medicare Program; Final Waivers in Connection with the Shared Savings Program. Fed Register. 2015;80(66725):66725-66745. October 29, 2015. Available at: <https://www.federalregister.gov/documents/2015/10/29/2015-27599/medicare-program-final-waivers-in-connection-with-the-shared-savings-program>
- ²⁰ Centers for Medicare and Medicaid Services. Fraud and Abuse Waivers. Updated February 1, 2021. Available at: <https://www.cms.gov/medicare/physician-self-referral/fraud-and-abuse-waivers>
- ²¹ Office of Inspector General, U.S. Department of Health and Human Services. Advisory Opinions. Available at: <https://oig.hhs.gov/compliance/advisory-opinions/>
- ²² Centers for Medicare and Medicaid Services. Law and Policy. Updated April 29, 2021. Available at: <https://www.cms.gov/OpenPayments/Law-and-Policy>
- ²³ Centers for Medicare and Medicaid Services. Next Generation ACO Model Coordinated Care Reward for Annual Wellness Visits Frequently Asked Questions. April 2019. Available at: <https://innovation.cms.gov/files/x/nextgenaco-ccrfaq.pdf>
- ²⁴ United States Government Accountability Office. CMS Innovation Center Model Implementation and Center Performance. March 2018. GAO-18-302. Available at: <https://www.gao.gov/assets/gao-18-302.pdf>
- ²⁵ Medicare and State Health Care Programs: Fraud and Abuse;

Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. 85 Federal Register 77684-77895. January 19, 2021. Codified at 42 CFR §1001.

- ²⁶ Gaus, C. Re: Comments on Notice of Proposed Rulemaking related to the Stark and Anti-kickback Statutes [OIG-0936-AA10-P and CMS-1720-P]. National Association of ACOs. December 31, 2019. Available at: <https://www.naacos.com/naacos-stark-aks-comments>
- ²⁷ Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations. 85 Federal Register 77492-77682. December 12, 2020. Codified at 42 CFR §411.
- ²⁸ National Association of ACOs. Re: Comments on Notice of Proposed Rulemaking related to the Stark and Anti-kickback Statutes [OIG-0936-AA10-P and CMS-1720-P]. December 31, 2019. Available at: <https://www.naacos.com/naacos-stark-aks-comments>
- ²⁹ The Center for Medicare & Medicaid Innovation. CMS Next Generation ACO Beneficiary Cost Sharing Support for Part B Medicare Services Frequently Asked Questions. Available at: <https://innovation.cms.gov/files/x/nextgenaco-costsharing-partbservices.pdf>
- ³⁰ Centers for Medicare and Medicaid Services. Medicare Shared Savings Program Skilled Nursing Facility 3-Day Rule Waiver Guidance. May 2021. Available at: <https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharedsavingsprogram/downloads/snf-waiver-guidance.pdf>
- ³¹ Siddiqui N, Streeter S, Jacobs E, Kieffer T. Beneficiary Engagement Toolkit. Prepared for The Center for Medicare & Medicaid Innovation. November 2019. Available at: <https://innovation.cms.gov/files/x/aco-beneficiary-engagement-toolkit.pdf>
- ³² Burnes D, Henderson CR Jr, Sheppard C, Zhao R, Pillemer K, Lachs MS. Prevalence of Financial Fraud and Scams Among Older Adults in the United States: A Systematic Review and Meta-Analysis. *Am J Public Health*. 2017;107(8):e13-e21. doi:10.2105/AJPH.2017.303821
- ³³ Inzerro A. ACOs Describe What's Involved When Implementing a SNF Waiver Program. *AJMC*. June 15, 2020. Available at: <https://www.ajmc.com/view/acos-describe-whats-involved-when-implementing-a-snf-waiver-program>
- ³⁴ Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2021. Available at: http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf