



MEMORANDUM

November 7, 2019

To: The Honorable Representative Roger Marshall, MD
Attention: Charlotte Pineda

From: Paulette C. Morgan, Specialist in Health Care Financing, pcmorgan@crs.loc.gov, 7-7317
Michele L. Malloy, Research Librarian, mmalloy@crs.loc.gov, 7-1927
Suzanne M. Kirchhoff, Analyst in Health Care Financing, skirchhoff@crs.loc.gov, 7-0658

Subject: Summary of H.R. 3107, the “Improving Seniors’ Timely Access to Care Act of 2019”

This memorandum responds to your request for a summary of H.R. 3107, the “Improving Seniors’ Timely Access to Care Act of 2019” as introduced on June 5, 2019, by Representative DelBene, and referred to the House Committees on Ways and Means, and Energy and Commerce on that date.¹ You also requested background information and current law relevant to H.R. 3107.²

Because these issues are of general interest to Congress, information contained in this memorandum may be used to respond to other congressional requests. However, information regarding your request will remain confidential.

The memorandum includes the following:

- A very brief overview of H.R. 3107,
- Background information on the Medicare program related to the modifications and additions made by H.R. 3107, including descriptions of coverage and payment,
- A discussion of prior authorization (PA) and its use in Medicare, in particular Medicare Advantage (MA) and Part D (Prescription Drug Program), and
- A detailed summary of the bill.

Brief Overview of H.R. 3107

H.R. 3107 would amend Title XVIII of the Social Security Act (SSA) to require Medicare Advantage (MA) plans to establish electronic PA processes that adhere to specified requirements, including “real-time” decisions for a subset of PA requests. Generally, PA is a process through which a physician or other

¹ See bill at Congress.gov, <https://www.congress.gov/bill/116th-congress/house-bill/3107>.

² In line with the scope of your request, CRS did not do an analysis of the possible impact of the legislation. This memorandum does not consider the potential effects of enactment such as changes in federal spending, or Medicare Advantage plan, provider, or supplier behaviors.

health care provider must obtain advance approval from the insurer, including a MA plan when appropriate, that payment will be made for a service or item furnished to an enrollee.

Under the bill, MA plans would be required to submit certain information about PAs to the Secretary of Health and Human Services (HHS Secretary), including data on denials, overturned decisions, and the average and median amount of time it took a plan to make a determination. Plans would be required to make the information available to others, as specified. The HHS Secretary would be required to promulgate regulations that establish standards with respect to MA plan use of PA to ensure (a) that MA PA policies are transparent, (b) that plans conduct annual reviews of PA policies, (c) that enrollees in MA plans receive continuity of care, (d) that PAs are made in a timely manner, and (e) MA plans provide support for providers and suppliers submitting PA requests. Finally, H.R. 3107 would prohibit PA in specific circumstances.

Background

Medicare is a federal program that pays for covered health care services of qualified beneficiaries.³ Medicare consists of four distinct parts:

- Part A (Hospital Insurance, or HI) covers inpatient hospital services, skilled nursing care, hospice care, and some home health services.
- Part B (Supplementary Medical Insurance, or SMI) covers physician services, outpatient services, durable medical equipment, and some home health and preventive services.
- Part C (Medicare Advantage, or MA) is a private plan option for beneficiaries that covers all required Parts A and B services, except hospice and organ acquisition for kidney transplants.⁴ MA plans may also offer additional benefits not covered under Parts A and B.
- Part D is a voluntary program that covers outpatient prescription drug benefits, either as a stand-alone prescription drug plan (PDP), or integrated with Part C benefits as an MA-PD.

Coverage

In general, for Medicare to pay for an item or service, the item or service must meet several criteria: it must be eligible for one of the defined Medicare benefit categories (e.g., hospital care, physician's services); it must not be an item that is specifically, statutorily excluded from coverage (e.g., hearing aids); and it must be "reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member."⁵ Alternatively, an item or service may be specified in statutes as being covered by Medicare even if it would not otherwise meet the above criteria (e.g., preventive services).

Exactly which specific items and services are considered "reasonable and necessary" and covered by the Medicare program can be determined nationally or locally. A national coverage determination (NCD) is a decision by the HHS Secretary that a particular item or service is reasonable and necessary, and therefore covered by Medicare nationally. In the absence of an NCD, Medicare administrative contractors (MACs)

³ CRS Report R40425, *Medicare Primer*.

⁴ SSA Section 1852(a)(1)(B). If an MA enrollee chooses to participate in hospice, or is eligible for an organ transplant, these options are paid for through original Medicare.

⁵ SSA Section 1862(a)(1)(A).

may issue local coverage determinations (LCD) that establish whether a particular service is reasonable and necessary, and therefore covered by Medicare within the contractor's service area. Among other elements, LCDs can include an explanation of the clinical circumstances under which an item or service is reasonable and necessary, what evidence is necessary to support a coverage request, and how providers can correctly code and submit claims.⁶

In general, the coverage determinations that apply to original fee-for-service (FFS) Medicare (Parts A and B) also apply to MA plans. However, there are situations where MA plans are allowed to standardize benefits or delay implementation. For example, if an MA plan service area spans more than one MAC region and therefore is subject to more than one coverage determination, the MA plan can choose to standardize its coverage policy based on the coverage determination that is most beneficial to the enrollee.⁷ In addition, if there is an NCD or legislative change that results in an expansion of coverage with a substantial cost to an MA plan, and the change was not taken into account during the yearly bidding process to determine MA plan payment (described below), the change would not apply to the MA plan until the first contract year after the change could be taken into account.⁸

Regarding Medicare Part D, in order for an outpatient prescription drug to be paid, it must meet the definition of a covered drug and it must also be included on the formulary of the Part D plan. Part D drugs are defined as: (1) outpatient prescription drugs approved by the Food and Drug Administration (FDA), and used for a medically accepted indication; (2) biological products that may be dispensed only upon a prescription and that are licensed under the Public Health Service Act (PHSA) and produced at a licensed establishment; (3) insulin (including medical supplies associated with the injection of insulin); and (4) vaccines licensed under the PHSA. Drugs can also be treated as part of a plan's formulary as the result of a beneficiary coverage determination or appeal.⁹

Certain drugs are excluded from Part D coverage by law, including drugs specifically excluded from coverage under the state-federal Medicaid program. The exclusion applies to: (1) drugs used for anorexia, weight loss, or weight gain; (2) fertility drugs; (3) drugs used for cosmetic purposes or hair growth; (4) drugs for symptomatic relief for coughs and colds; (5) prescription vitamins and minerals; and (6) covered drugs when the manufacturer requires, as a condition of sale, that associated tests be purchased exclusively from the manufacturer. Drugs used for the treatment of sexual or erectile dysfunction are excluded from coverage unless they are used to treat another condition for which the drug has been approved by the FDA.

There is no central formulary, or list of covered drugs, in the Medicare Part D program. However, Part D plans must cover at least two drugs in each class and category and substantially all drugs in six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic (cancer) classes.¹⁰

Payment

Payment under the Medicare program for covered benefits follows statutory requirements, as implemented through rules. Some benefits, such as physician services and some durable medical

⁶ The Medicare Coverage Database on the CMS website allows one to find NCDs, LCDs, or both, by geographic area, or by searching for key terms, or codes. Coverage policies in some cases can be very detailed and assume greater-than-lay-person's understanding of medicine or technology making them challenging to read by individuals without medical training.

[<https://www.cms.gov/medicare-coverage-database/>]

⁷ SSA Section 1852(a)(2)(C).

⁸ SSA Section 1852(a)(5).

⁹ See covered drug and Part D drug at 42 CFR Section 423.100.

¹⁰ CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

equipment, are paid through fee schedules, which are lists of Medicare payments for specific items and services that are calculated according to statutorily specified formulas and take into account the labor and capital resources required to provide the item or service. In such cases, the total payment depends on the number and volume of items and services furnished and billed. Other services, such as inpatient hospital care and home health care, are paid under prospective payment systems, where payment amounts are pre-determined for a defined period and/or diagnosis, and are based on an episode of care rather than a measure of the resources used in treating the patient. Other payments, such as those for MA plans and Part D plans, are based on bids and/or benchmarks, which are then used to determine per person monthly payments for providing covered benefits. Below, the payment mechanisms for Medicare Part C and Part D are explained in more detail.

Medicare Advantage Payments

As discussed above, MA plans are paid a per-person monthly amount by Medicare.¹¹ The HHS Secretary determines a plan's payment by comparing its bid to a benchmark. A *bid* is the plan's estimated cost of providing Medicare-covered services (excluding hospice, and specified organ acquisition, but including the cost of medical services, administration, and profit). A *benchmark* is the maximum amount the federal government will pay for providing those services in the plan's service area, and is based on a percentage of per capita spending in original (FFS) Medicare. If a plan's bid is less than the benchmark, the plan's payment equals its bid plus a rebate. The rebate must be returned to enrollees in the form of additional benefits, reduced cost sharing, reduced Medicare Part B or Part D premiums, or some combination of these options. If a plan's bid is equal to or above the benchmark, its payment equals the benchmark amount; each enrollee in that plan will pay an additional premium that is equal to the amount by which the bid exceeds the benchmark. Additionally, payments to plans are risk adjusted to take into account the demographic and health history of those who actually enroll in the plan.¹²

Part D Payments

Similar to payments for MA plans, Medicare makes risk-adjusted payments to Part D prescription drug plan sponsors (insurers) on a monthly prospective basis based on the revenue estimates in the sponsors' annual plan bids. Bids are based on a plan's estimated cost for providing "standard coverage" to an enrollee in average health. The Part D standard benefit is defined in statutes, and updated annually to account for Part D drug price inflation. In practice, although plan bids are based on "standard coverage," most plan sponsors choose to offer alternative coverage (such as coverage with tiered formulary cost sharing for prescription drugs), which must be at least actuarially equivalent to standard coverage; or enhanced coverage, which has a higher actuarial value. Unlike MA plans, payments to Part D plans include not only per-person direct subsidy payments, adjusted for health risk and beneficiary premiums, but also low-income subsidies (based on enrollee income and assets), and projected reinsurance payments.¹³

¹¹ Medicare Reasonable Cost plans are also private plans that offer Medicare covered benefits to beneficiaries who enroll in their plans. Unlike MA plans, Cost plans are paid based on the actual cost of services provided to enrollees, rather than through monthly capitated payments. Rules pertaining to PA are different for Cost plans, and are outside the scope of this memorandum. For more information, see Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Chapter 17f-Subchapter F - Benefits and Beneficiary Protections*, October 28, 2005, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=ascending>.

¹² See also, CRS Report R45494, *Medicare Advantage (MA)—Proposed Benchmark Update and Other Adjustments for CY2020: In Brief*.

¹³ See also, CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

In part because MA and Part D plans are paid on a capitated basis and are at risk, to some extent, if costs of providing benefits to enrollees exceed plan revenues, plan sponsors have an incentive to provide more efficient health care and to reduce unnecessary or harmful care. To do so, plans may negotiate with providers, hospitals, or drug manufacturers to reduce the prices they pay to entities in their networks. Plans may also use other management techniques to reduce costs. For example, MA plan enrollees may be required to see a primary care physician before being referred to a specialist. Enrollees may be required to try a less expensive drug or service before being covered for a more expensive one (i.e., step therapy). Enrollees also may be required to seek a PA from a plan before receiving an item, service, or drug, as discussed below.

Prior Authorization

Prior authorization for MA plans is described by HHS as a “process through which the physician or other health care provider is required to obtain advance approval from the plan that payment will be made for a service or item furnished to the enrollee. Unless specified otherwise with respect to a particular item or service, the enrollee is not responsible for obtaining (prior) authorization.”¹⁴ To satisfy a PA requirement, a physician or health care provider must demonstrate compliance with coverage and payment rules before an item or service is provided to the beneficiary, rather than after. If a PA is denied, an individual, or his or her physician or health care provider, may appeal the decision through a process that allows for multiple levels of review and appeal.¹⁵ Prior authorization is a management technique that can reduce unnecessary care, potentially harmful care, improper payments, or expenditures. However, PA can be burdensome and costly to providers and patients, and it may have the potential to delay care or discourage beneficiaries from receiving care if an item or service is initially denied.

Though primarily associated with private insurers, PA is used in original Medicare through special demonstrations (repetitive scheduled non-emergency ambulance services), and one permanent program that applies to selected pieces of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).¹⁶ The purpose of the PA requirements generally is to reduce expenditures, unnecessary utilization, and improper payments. A recent Government Accountability Office (GAO) Report found that PA used in original Medicare decreased program expenditures for items and services.¹⁷ While PA reduced unnecessary utilization, the report also found that some DMEPOS suppliers experienced challenges in obtaining the necessary documentation from referring physicians to submit for the PA requests.

¹⁴ Department of Health and Human Service, Centers for Medicare & Medicaid Services, *Publication 100-16 - Medicare Managed Care Manual*, Chapter 4 - Benefits and Beneficiary Protections, April 22, 2016, Section 110.1.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

¹⁵ See also, Medicare Managed Care Appeals and Grievances, <https://www.cms.gov/Medicare/Apppeals-and-Grievances/MMCAG/index.html>.

¹⁶ See, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-of-Repetitive-Scheduled-Non-Emergent-Ambulance-Transport-.html>, and <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/DMEPOS/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html>.

¹⁷ U.S. Government Accountability Office, *Medicare: CMS Should Take Action to Continue Prior Authorization Efforts to Reduce Spending*, GAO-18-341, April 2018, p. 1, https://www.gao.gov/products/GAO-18-341?mobile_opt_out=1. The report identified additional demonstrations that were either rolled into the permanent program (certain power mobility devices), or had ended, or ended subsequent to publication (home health, non-emergency hyperbaric oxygen therapy.)

Prior Authorization in Medicare Advantage

Medicare statutes, regulations, and program manuals specify requirements and limitations with respect to the use of PA in MA plans. Medicare Advantage plans, for example, are prohibited from implementing utilization management protocols (such as PA, referrals for specialist services, or step therapy) that create inappropriate barriers to needed care.¹⁸ Each plan's PA and other utilization management policies are submitted to CMS and evaluated as part of the Plan Benefit Package (PBP) at the beginning of each June as part of the yearly contracting process.¹⁹ Regardless of the any PA policy, MA plans are required to provide coverage for emergency services that meet the statutory definition of an emergency.²⁰ In addition to these coverage-related requirements, MA plans are also subject to certain disclosure requirements. Plans are required to disclose specified information, in a clear, accurate, and standardized format, to each enrollee at the time of enrollment and yearly thereafter, including "rules regarding prior authorization or other review requirements that could result in nonpayment."²¹ Program manuals provide greater detail with respect to disclosure requirements, such as the documents that are required to be available on the plan website (including utilization management and PA forms for beneficiaries and physicians)²² and required components for the Summary of Benefits documents (which are to include a notation when a service requires a physician referral or prior authorization).²³ The Medicare Plan Finder on the Medicare.gov website also may indicate if advance plan approval is required for certain items or services. Plans also are required to provide information about the appeal processes to follow if an item or service is initially denied.²⁴

While MA plans are not required to use PA policies, recent research indicates that 4 out of 5 MA enrollees in 2018 were in an MA plan that used them, and that PA policies were most often used with respect to DME or skilled nursing facility stays.²⁵ Another recent study examined rates of coverage denials in MA plans from 2014 through 2016. The study found that of all of the prior authorizations *and payment denials*²⁶ by the MA plans included in the study, enrollees and providers appealed one percent of those

¹⁸ Department of Health and Human Service, Centers for Medicare & Medicaid Services, *Publication 100-16 - Medicare Managed Care Manual*, Chapter 4 - Benefits and Beneficiary Protections, April 22, 2016, Section 110.1.1, <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>.

¹⁹ Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2020 Draft Call Letter*, Part 2, January 30, 2019, p. 103, <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2020Advance.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending>.

²⁰ SSA Section 1852(d)(1)(E).

²¹ SSA Section 1852(c)(1)(G). Regulations can be found at 42 CFR Section 422.111(b)(7).

²² Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicare Communication and Marketing Guidelines*, September 5, 2018, pp. 18-19, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html>.

²³ Ibid pp. 71-72.

²⁴ <https://www.medicare.gov/claims-appeals/file-an-appeal/appeals-if-you-have-a-medicare-health-plan>.

²⁵ Gretchen Jacobson and Tricia Newman, *Prior Authorization in Medicare Advantage Plans: How Often is it Used?*, Henry J. Kaiser Family Foundation, Data Note, October 2018, <https://www.kff.org/medicare/issue-brief/prior-authorization-in-medicare-advantage-plans-how-often-is-it-used/>.

²⁶ Daniel R. Levinson, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concern About Service and Payment Denials*, Department of Health and Human Services, Office of Inspector General, OEI-09-16-00410, September 2018, <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>. This report included examination of 24 million prior authorization requests that had been denied, along with 424 million payment requests for services that had already been provided to beneficiaries and for which payment had been denied. Similar results (74% of appeals overturned or partially overturned) were found in an OIG study on Medicare Part D plans. Suzanne Murrin, *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescription Drugs*, Department of Health and Human Services Office of the Inspector General, OEI-

denials to the first level of appeal. Of those who appealed to the first level, 75% of those denials were overturned by the MA plans, and independent reviewers at higher levels of the appeal process overturned additional denials.²⁷ Study authors recommended, in part, greater oversight of MA plans with high overturn rates, or low appeal rates. In contrast, industry representatives examining prior authorization have suggested alternative approaches to improving PA by, in part, focusing on more selective application of PA policies, reviewing and adjusting PA policies that are no longer warranted, improving communication between plans, providers, and patients, and automating the PA process to encourage efficiency.

Unlike Part D plans, as discussed below, MA plans do not have an electronic PA (ePA) requirement. A recent report by the Council for Affordable Quality Healthcare (CAQH)²⁸ examined adoption of electronic administrative transactions, such as ePA, in the health care industry overall (i.e., not specifically MA). In 2018, CAQH found that 51% of PAs were processed manually, by phone, fax, or e-mail, while 12% were processed completely electronically, and 36% were processed using a combination of manual and electronic means.²⁹ One explanation for the ePA adoption rates may be due to certain state rules, which specify that plans must use manual means to notify enrollees if a PA request is declined. Another reason is that vendors of health care administration software are still developing support for electronic PA transactions, though they indicate that they are hampered by a lack of a federal attachment standard (to attach clinical information to the ePA). Some health plans have responded by developing their own web portals for ePA transactions, but that process requires physicians to switch between their electronic health record system where clinical records reside, and each plan's portal. The CAQH report indicates that adoption of ePA systems (instead of manual systems) would decrease the administrative cost of processing PAs.³⁰ However, there is a cost to administering or upgrading to a new system with ePA capabilities.

Prior Authorization in Medicare Part D³¹

As discussed above, there is no central formulary in Part D, although each plan must provide a detailed formulary, which is a list of drugs covered by the plan and the terms under which they are covered.³² Part D plan formularies must include at least two drugs in each class and category, and substantially all drugs

09-16-00411, September 2019.

²⁷Daniel R. Levinson, *Medicare Advantage Appeal Outcomes and Audit Findings Raise Concern About Service and Payment Denials*, Department of Health and Human Services, Office of Inspector General, OEI-09-16-00410, September 2018, <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

²⁸ CAQH is “a non-profit alliance of health plans and related associations”. They “develop and implement shared, industry-wide initiatives to eliminate long-term business inefficiencies”. Members include AHIP, Aetna, Anthem, BlueCross BlueShield, Cigna, Humana, Kaiser, UnitedHealth. <https://www.caqh.org/about/about-caqh>.

²⁹ These data are based on a survey of medical health plans and dental health plans covering “nearly half of the insured U.S. population in the year studied.” CAQH, *2018 CAQH Index: A Report of HealthCare Industry Adoption of Electronic Business Transactions and Cost Savings.*, July 2018, pp. 10-12, <https://www.caqh.org/explorations/caqh-index-report-0>.

³⁰ .” CAQH, *2018 CAQH Index: A Report of HealthCare Industry Adoption of Electronic Business Transactions and Cost Savings.*, July 2018, p. 11, <https://www.caqh.org/explorations/caqh-index-report-0>.

³¹ As H.R. 3107 does not amend the Part D of the Social Security Act, the description of PA under Part D plans in this memorandum is an abbreviated summary of the relevant policies.

³² CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, “Part D Drugs and Formulary Requirements,” Section 30.2.1, Rev. January 15, 2016, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. Part D sponsors may use existing drug classification systems, such as those from U.S. Pharmacopeia (USP) and American Hospital Formulary Service (AHFS), or create their own.

in six protected classes.³³ Part D plan sponsors must use Pharmacy and Therapeutics (P&T) Committees to develop formularies based on scientific evidence and standards of practice. Plans manage beneficiary access to drugs through such formulary utilization tools as requiring a beneficiary to obtain PA from a plan before filling a prescription, setting quantity limits on prescriptions, and instituting step therapy. According to CMS, Part D plans are encouraged to consistently utilize PA for drugs prescribed for non-Part D covered uses and to ensure that Part D drugs are only prescribed when medically appropriate. CMS reviews plan formularies each year to ensure they include the required mix of drugs and do not discriminate against enrollees based on health conditions.

Part D enrollees have the right to appeal drug coverage determinations, file grievances against plan sponsors, and file complaints regarding quality of care. Part D plan sponsors must provide enrollees with written information about their rights, and institute standard and expedited procedures for addressing coverage issues.³⁴ Coverage issues can include coverage determinations, which is any decision (whether an approval or denial) made by a plan sponsor with regard to covered benefits. An enrollee request to satisfy or challenge a formulary PA requirement is considered to be a coverage determination.³⁵

Disclosure requirements in Medicare program manuals (discussed above in relation to beneficiary education and availability of information in MA plans) also apply to Part D plans. In addition, Part D plans must sponsor toll-free call centers staffed with live customer representatives who are available during normal business hours to respond to questions about coverage determinations, exceptions, PAs, and appeals.³⁶

Part D plans must also meet requirements for electronic or e-prescribing, which is defined by CMS as the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.³⁷ E-prescribing allows insurers, prescribers, and pharmacies to quickly exchange information about prescribed drugs, patient medical histories, and other pertinent information.

CMS regulations and contract provisions require Part D plan sponsors to support e-prescribing systems that allow for transmission of information about enrollee eligibility, plan benefits (including drugs on the plan formulary and formulary requirements including any prior authorization requirements), the drug being prescribed or dispensed and other drugs listed in the medication history, and the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.³⁸ Part D plans must base their e-prescribing programs on standards developed by the National Council for Prescription Drug Programs (NCPDP SCRIPT). The NCPDP is an accredited standards development organization.³⁹

The Part D foundational e-prescribing regulations were published in 2005. The regulations have been updated a number of times to incorporate new data and revisions to the NCPDP system, or in response to statutory requirements.⁴⁰ In May 2019, CMS issued final rules requiring Part D sponsors, no later than

³³ Ibid.

³⁴ CMS, *Medicare Appeals*, <http://www.medicare.gov/Pubs/pdf/11525.pdf>.

³⁵ CMS, *Medicare Part D Manual*, “Chapter 18 - Part D Enrollee Grievances, Coverage Determinations, and Appeals,” Rev. April 12, 2014, Section 30 and 30.1 Available at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminationsandExceptions.html>.

³⁶ Ibid. p 23.

³⁷ 42 CFR §423.159.

³⁸ See 42 CFR §423.505(b)(6) for Part D contract requirements. See 42 CFR §423.160 for CMS standards for electronic prescribing. See also Social Security Act 1860D-4(e).

³⁹ NCPDP, “About Us,” <https://www.ncpdp.org/About-Us>.

⁴⁰ CMS, “E-Prescribing,” <https://www.cms.gov/Medicare/E-Health/Eprescribing/index.html?redirect=/eprescribing>; and CMS,

January 1, 2021, to implement one or more electronic real-time benefit tools (RTBT) that include secure electronic transmission of prior authorization (ePA) requests from prescription drug prescribers, in addition to responses from PDP or MA-PD plans to the prescribers.⁴¹ A subsequent proposed rule published June 19, 2019, would specify that the electronic standard to be used for the ePA transaction would be “version 2017071” of the NCPDP SCRIPT standard.⁴²

Summary of H.R. 3107, the “Improving Seniors’ Timely Access to Care Act of 2019”

Section 1. Short Title.

The act is cited as the “Improving Seniors’ Timely Access to Care Act of 2019”.

Section 2. Sense of the Congress.

This provision of the bill summarizes the sense of Congress that PA should be streamlined through electronic transmission for services funded under Medicare, Medicaid, and federally contracted private insurance companies, in order to improve patient access to medically appropriate care and reduce administrative burden through automation informed by clinical decision support. The Sense of the Congress section states that there should be increased transparency for beneficiaries and providers, and increased oversight by CMS, and that PA is a tool that can be used responsibly to prevent unnecessary care and promote safe and evidence-based care.

Section 3. Establishing Requirements with Respect to the Use of Prior Authorization under Medicare Advantage Plans.

Provision

H.R. 3107 would amend SSA Section 1852 by adding a new section that would require MA plans to establish electronic prior authorization programs, meet specified transparency requirements, meet beneficiary protection standards, and prohibit PA in specified circumstances.

Electronic Prior Authorization Program.

This provision would require MA plans to establish electronic PA processes that provide for the secure electronic transmission of both PA requests from health care professionals to the MA plan, as well as the

⁴¹ Adopted Standards and Transactions,” <https://www.cms.gov/Medicare/E-Health/Eprescribing/Adopted-Standard-and-Transactions.html>. CMS, *Federal Register*, “Medicare Program; E-Prescribing and the Prescription Drug Program; Final Rule,” November 7, 2005, p. 67568, <https://www.gpo.gov/fdsys/pkg/FR-2005-11-07/pdf/05-22026.pdf>. The “Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act” or the SUPPORT Act included requirements to upgrade e-prescribing standards to ensure secure electronic prior authorization request and response transmissions.

⁴² 42 C.F.R. 423.160(b)(7); SSA Section 1860D-4(e). Though MA does not have a separate electronic prescribing program, an MA provision at SSA Section 1857(j)(7) promotes e-prescribing by allowing a separate payment from MA-PD plans to participating physicians that prescribe drugs in accordance with the electronic prescription drug program under Section 1860D-4(e).

⁴³ Department of Health and Human Services, “Medicare Program: Secure Electronic Prior Authorization for Medicare Part D,” 84 *Federal Register* 28450, June 19, 2019, <https://www.federalregister.gov/documents/2019/06/19/2019-13028/medicare-program-secure-electronic-prior-authorization-for-medicare-part-d>.

corresponding response from the plan to the professionals. With respect to the electronic PA request, the transmission would be required to be capable of including clinical information, as the medical professional determines appropriate, to support the coverage of the item or service. The provision would not allow facsimiles, proprietary payer portals that do not meet standards specified by the HHS Secretary, nor electronic forms to qualify as secure electronic transmissions.

The HHS Secretary would be required to adopt technical standards for secure electronic transmissions, and do so in consultation with standard-setting organizations determined appropriate by the HHS Secretary, as well as health care professionals, MA organizations, and health information technology software vendors. In adopting the standards, the HHS Secretary would be required to ensure that the electronic transmissions support attachments containing applicable clinical information. The HHS Secretary would also be required to prioritize the adoption of standards that encourage integration of the electronic PA program into established electronic health record systems. The standards established by the HHS Secretary would also be required to be consistent with health care industry standards, with respect to attachments, data, and operating rules for the transmissions.

The electronic PA program would be required to provide real-time decisions with respect to specified PA requests, where “real-time” would be defined by the Secretary. Requests subject to real-time decisions would be those that the HHS Secretary identified as requests for items and services that were routinely approved by the plan; the HHS Secretary would be required to identify those items and services by no later than the first Monday of April prior to the calendar year concerned. In identifying PA requests that are routinely approved, the HHS Secretary would be required to use information provided by MA plans as part of the transparency requirements described below, if available, and also would be required to issue a request for information from providers, suppliers, patient advocacy organizations, and other stakeholders. To be eligible for real-time decisions, specified PA requests also would be required to contain all of the information required by the plan to evaluate the criteria that plans use to make the PA determinations.

Transparency Requirements.

H.R. 3107 would require MA plans to adhere to specified transparency requirements. MA plans would be required to submit the following to the HHS Secretary at least annually: (a) a list of all covered Medicare Parts A and B benefits that are subject to a PA requirement; (b) the percentage of PA requests approved during the previous year by the plan by item and service; (c) the percentage of PA requests that were initially denied and that were subsequently appealed, and the percentage of appealed PA requests that were overturned, by item and service; (d) the average and median amount of time (in hours) that elapsed during the previous plan year between the submission of the PA request and the determination by the plan, by item and service, but excluding any request that did not contain the information the plan required; and (e) such other information as the HHS Secretary determines appropriate after consultation with and comment from stakeholders.

In addition to submitting this information to the HHS Secretary, each plan would be required to publish the information before open enrollment each year on a publicly available website. The plan would be required to provide a website address for the PA transparency information in any enrollment materials distributed by the plan, and would be required to update the website in a timely manner. The plan would be required to provide the same specified PA transparency information as part of any contract materials to any provider or supplier who seeks to participate under the plan. The MA plan also would be required to provide any policies or procedures used by the plan for making PA determinations.

For each provider or supplier already participating under the plan, the MA plan would be required to provide access to the criteria used for making PA determinations, including an itemization of the medical and other documentation required to be submitted by a provider or supplier with respect to such request, except to the extent that provision of access to such criteria would disclose proprietary information about

the plan, as determined by the HHS Secretary. Not later than the end of the second year beginning on or after the date of enactment of this section, and biennially thereafter, the HHS Secretary would be required to submit a report to Congress describing the above specified PA transparency information for the relevant period.

Beneficiary Protection Standards.

H.R. 3107 would require the HHS Secretary to specify standards for use of PA by MA plans through notice and comment rulemaking, to ensure following:

- (a) adoption of transparent programs developed in consultation with providers and suppliers participating under the plan that promote the modification of such requirements based on the performance of providers and suppliers with respect to adherence to evidence-based medical guidelines and other quality criteria;
- (b) requirements for annual reviews of items and services for which prior authorization requirements are imposed under the plans, through a process that takes into account input from participating providers and suppliers and is based on analysis of past PA requests and current clinical criteria;
- (c) continuity of care for individuals transitioning to, or between, coverage under the plan in order to minimize any disruption to ongoing treatment attributable to the PA requirements of the plan;
- (d) requirements that the MA plan makes timely PA determinations, provides rationale for denials, and ensures requests are reviewed by qualified medical personnel; and
- (e) that plans assist providers and suppliers in submitting the information necessary to enable plans to make PA determinations in a timely manner.

Prohibition on Prior Authorization with Respect to Certain Items and Services.

H.R. 3107 would prohibit MA plans from imposing additional PA requirements with respect to any surgical procedure or otherwise invasive procedure, as defined by the HHS Secretary, and for any item furnished as part of a surgical or invasive procedure, if the procedure or item is furnished during a peroperative period and either of two conditions apply: (a) a PA was received from the MA plan before the surgical or otherwise invasive procedure (or item furnished as part of the surgical or otherwise invasive procedure) was furnished, or (b) a PA was not required by the plan.