

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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Provider Enrollment Requirements for Writing Prescriptions for Medicare Part D Drugs

Note: The article was revised on November 16, 2016, to show a phased approach to enforcement that will begin in the second calendar quarter of 2017 and end with full implementation and enforcement of the Part D prescriber enforcement requirement on January 1, 2019.

Provider Types Affected

This MLN Matters® Special Edition is intended for physicians, dentists, and other eligible professionals who write prescriptions for Medicare beneficiaries for Medicare Part D drugs. The article is also directed to Medicare Part D plan sponsors.

Provider Action Needed

The Centers for Medicare & Medicaid Services (CMS) finalized CMS-4159-F, “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” on May 23, 2014. CMS later published CMS-6107-IFC, “Medicare Program; Changes to the Requirements for Part D Prescribers,” an interim final rule with comment (“IFC”), that made changes to the Final Rule (CMS-4159-F), on May 6, 2015. Together, these rules require virtually all physicians and other eligible professionals, including dentists, who write prescriptions for Part D drugs to be enrolled in an approved status or to have a valid opt-out affidavit on file for their prescriptions to be coverable under Part D, except in very limited circumstances. To allow sufficient time for the prescribers to enroll in Medicare and the Part D sponsors and the Pharmacy Benefit Managers (PBMs) to make the complex system enhancements needed to

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comply with the prescriber enrollment requirements, CMS announced a delay in enforcement of this rule until February 1, 2017.

While the full implementation date is January 2019, CMS encourages all providers who prescribe Part D drugs, but are not yet enrolled or validly opted out of Medicare, to enroll in the Medicare Program. Enrollment information is available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Part-D-Prescriber-Enrollment-About.html>.

While CMS is committed to the implementation of the prescriber enrollment requirements, CMS also recognizes the need to minimize the impact on the beneficiary population and ensure beneficiaries have access to the care they need. **To strike this balance, CMS will implement a multifaceted, phased approach which will align full enforcement of the Part D prescriber enrollment requirements with other ongoing CMS initiatives. Full enforcement of the Part D prescriber enrollment requirement is January 1, 2019.**

In the lead-up to the January 1, 2019 full implementation date, CMS will undertake the following incremental strategic actions designed to increase on-going prescriber enrollment, while protecting beneficiaries and the Medicare program.

- Precluded Providers - Prescriptions will be denied at the point of sale from sanctioned providers including, but not limited to, providers that are currently excluded by the OIG, revoked by the Medicare program and non-enrolled providers with a felony conviction within the last 10 years. (Implementation in Second Quarter 2017)
- Easy Enroll Application Process - CMS will make an easy enrollment application process to enable providers to quickly enroll in Medicare. This process will allow providers to review, update, electronically sign and submit a pre-populated enrollment application online. (Implementation in Second Quarter 2017)
- Targeted Risk-Based Prescriber Outreach - CMS will begin targeted, prioritized risk-based outreach and education. This prioritized approach will include direct mailings and coordination with the Part D plans to enroll these prescribers. (Implementation in Second Quarter 2017)
- Direct Mailing to all Non-Enrolled Providers - CMS will target and send direct mailings via email and/or paper to all prescribers that are not enrolled in the program. In addition, direct mailing notifications will be triggered for unenrolled providers based on PDE events. (Implementation in Third Quarter 2017)
- Current Education and Outreach - CMS will continue with the current education and outreach efforts including such activities as stakeholder meetings and conferences, assembly meetings, and presentations. (Continuously on-going)

The purpose of these rules are to ensure that Part D drugs are prescribed only by physicians and eligible professionals who are qualified to do so under state law and under the requirements of the Medicare program and who do not pose a risk to patient safety. By implementing these rules, CMS is improving the integrity of the Part D prescription drug program by using additional tools to reduce fraud, waste, and abuse in the Medicare program. Prescribers who are determined to have a pattern or practice of prescribing Part D

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drugs that are abusive and represents a threat to the health and safety of Medicare enrollees or fails to meet Medicare requirements will have their billing privileges revoked under 42 USC 424.535 (a)(14).

Background

If you write prescriptions for covered Part D drugs and you are not already enrolled in Medicare in an approved status or have a valid record of opting out, you should submit an enrollment application or an opt-out affidavit to your Medicare Administrative Contractor (MAC) as soon as possible, so that the prescriptions you write for Part D beneficiaries are coverable as Medicare begins to enforce this requirement on February 1, 2017 with full implementation and enforcement slated for January 1, 2019.

To enroll in Medicare for the limited purpose of prescribing:

You may submit your enrollment application electronically using the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) located at <https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/internetbasedpecos.html> or by completing the paper CMS-855O application, which is available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855o.pdf>, which you must submit to the MAC that services your geographic area. Note that there is no application fee required for your application submission. For step-by-step instructions, refer to the PECOS how-to guide, available at <http://go.cms.gov/orderreferhowtoguide> or watch an instructional video at <http://go.cms.gov/videotutorial>.

The CMS-855O is a shorter, abbreviated form and takes minimal time to complete. While the CMS-855O form states it is for physicians and non-physician practitioners who want to order and certify, it is also appropriate for use by prescribers, who want to enroll to also prescribe Part D drugs. (CMS is in the process of updating the CMS-855O form). If you do not see your specialty listed on the application, please select the Undefined Physician/Non-Physician Type option and identify your specialty in the space provided.

Note: Dentists are recognized by Medicare as physicians and should select the “Part B Physician Specialties” option and specify General Dentist in the free form text box.

The average processing time for CMS-855O applications submitted online is 45 days versus paper submissions which is 60 days. However, your application could be processed sooner depending on the MAC’s current workload.

To enroll to bill for services (and prescribe Part D drugs):

To enroll in Medicare to bill for your services, you may complete the CMS-855I application. The CMS-855R should also be completed if you wish to reassign your right to bill the Medicare program and receive Medicare payments for some or all of the services you render to Medicare beneficiaries. All actions can be completed via PECOS or the paper enrollment application. For more information on enrolling in Medicare to bill for services refer to https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/MedEnroll_PECOS_PhysNonPhys_FactSheet_ICN903764.pdf.

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If you are a physician or non-physician practitioner who wants to opt-out of Medicare, you must submit an opt-out affidavit to the MAC that services your geographic area. Physicians and non-physician practitioners should be aware that if they choose to opt-out of Medicare, they are **not** permitted to participate in a Medicare Advantage Plan. In addition, once a physician or non-physician practitioner has opted out they are not permitted to terminate their opt-out affidavit early. Section 1802(b)(3)(B)(ii) of the Act establishes the term of the opt-out affidavit. The Act does not provide for early termination of the opt-out term. Under CMS regulations, physicians and practitioners who have not previously submitted an opt-out affidavit under Section 1802(b)(3) of the Act, may choose to terminate their opt-out status within 90 days after the effective date of the opt-out affidavit, if the physician or practitioner satisfies the requirements of 42 CFR § 405.445(b). No other method of terminating opt-out status before the end of the two year opt-out term is available.

Prior to enactment of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), physician/practitioner opt-out affidavits were only effective for 2 years. As a result of changes made by MACRA, valid opt-out affidavits signed on or after June 16, 2015, will automatically renew every 2 years. If physicians and practitioners that file affidavits effective on or after June 16, 2015, do not want their opt-out to automatically renew at the end of a two year opt-out period, they may cancel the renewal by notifying all MACs with which they filed an affidavit in writing at least 30 days prior to the start of the next opt-out period. Valid opt-out affidavits signed before June 16, 2015 will expire 2 years after the effective date of the opt out. If physicians and practitioners that filed affidavits effective before June 16, 2015, want to extend their opt out, they must submit a renewal affidavit within 30 days after the current opt-out period expires to all MACs with which they would have filed claims absent the opt-out. For more information on the opt-out process, refer to MLN Matters® article SE1311, titled “Opting out of Medicare and/or Electing to Order and Certify Items and Services to Medicare Beneficiaries,” which is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1311.pdf> and https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Provider-Partnership-Email-Archive-Items/2015-06-25-eNews.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending&imagelink=v#_Toc422891549.

CMS would like to highlight the following limitations that apply to billing and non-billing providers:

- A resident is defined in 42 CFR § 413.75 as an intern, resident, or fellow who participates in an approved medical residency program, including programs in osteopathy, dentistry, and podiatry, as required in order to become certified by the appropriate specialty board. Interns, residents, and fellows may enroll in Medicare to prescribe if the state licenses them. Licensure can include a provisional license or similarly- regulated credential. Un-licensed interns, residents, and fellows must specify the teaching physician who is enrolled in Medicare as the authorized prescriber on a prescription for a Part D drug (assuming this is consistent with state law). Licensed residents have the option to either enroll themselves or use the teaching physician’s name on prescriptions for Part D drugs, unless state law specifies which name is to be used. CMS strongly encourages teaching physicians and facilities to ensure that the NPI

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of the lawful prescriber under state law is included on prescriptions to assist pharmacies in identifying the correct prescriber and avoid follow up from the pharmacies, which experience rejected claims from Medicare Part D plans due to missing or wrong prescriber NPIs on the claims.

- The prescriber enrollment requirements also apply to physicians and non-physician practitioners who write prescriptions for Part D drugs and are employed by a Part A institutional provider (e.g., hospital, Federally Qualified Health Center (FQHC), Rural Health Center (RHC)). Since Part A institutional providers may bill for services provided by an employed physician or non-physician practitioner, the physician or non-physician practitioner may not have separately enrolled, unless he or she is also billing for Part B services. Therefore, if the physician or non-physician practitioner prescribes Part D drugs as an employee of the institutional provider, he or she must be enrolled in an approved status for their prescriptions to be coverable under Part D beginning June 1, 2016.
- “Other authorized prescribers” are exempt from the Medicare Part D prescriber enrollment requirement. In other words, prescriptions written by “other authorized prescribers are still coverable under Part D, even if the prescriber is not enrolled in or opted out of Medicare. For purposes of the Part D prescriber enrollment requirement only, “other authorized prescribers” are defined as individuals other than physicians and eligible professionals who are authorized under state or other applicable law to write prescriptions but are not in a provider category that is permitted to enroll in or opt-out of Medicare under the applicable statutory language. CMS believes “other authorized prescribers” are largely pharmacists who are permitted to prescribe certain drugs in certain states, but based on the applicable statute, pharmacists are not able to enroll in or opt-out of Medicare.

If you believe you are an “other authorized prescriber” and are not a pharmacist, please contact providerenrollment@cms.hhs.gov. In addition, CMS strongly recommends that pharmacists in particular make sure that their primary taxonomy associated with their NPI in the National Plan & Provider Enumeration System (NPPES) reflects that they are a pharmacist. To review and update your NPPES information, please go to the National Plan & Provider Enumeration System webpage at <https://nppes.cms.hhs.gov/NPPES/Welcome.do>. Upon enforcement of the regulation, Part D plans will need to be able to determine if the prescriber is a pharmacist in order to properly adjudicate the pharmacy claim at point-of-sale.

In an effort to prepare the prescribers and Part D sponsors for the first phase February 1, 2017 enforcement date, CMS has made available an enrollment file that identifies physician and eligible professional who are enrolled in Medicare in an approved or opt-out status. However, the file does not specify if a particular prescriber is eligible to prescribe, as prescribing authority is largely determined by state law. The enrollment file is available at <https://data.cms.gov/dataset/Medicare-Individual-Provider-List/u8u9-2upx>. The file contains production data but is considered a test file since the Part D prescriber enrollment requirement is not yet applicable. An updated enrollment

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file will be generated every two weeks, with a purposeful goal of providing updates twice a week by the date of enforcement.

The file displays physician and eligible professional eligibility on and after November 1, 2014, (that is, currently enrolled, new approvals, or changes from opt-out to enrolled as of November 1, 2014). Any periods, prior to November 1, 2014, for which a physician or eligible professional was not enrolled in an approved or opt-out status will not be displayed on the enrollment file. However, any gaps in enrollment after November 1, 2014, for which a physician or eligible professional was not enrolled in an approved or opt-out status will be reflected on the file with its respective effective and end dates for that given provider. For opted out providers, the opt-out flag will display a Y/N (Yes/No) value to indicate the periods the provider was opted out of Medicare. The file will include the provider's:

- (NPI)
- First and Last Names
- Effective and End Dates
- Opt-out Flag

Example 1– Dr. John Smith's effective date of enrollment is January 1, 2014. Since he was enrolled prior to the generation of the test file, his effective date will display as November 1, 2014. Dr. Smith submits an enrollment application to voluntarily withdraw from Medicare effective December 15, 2014. Dr. Smith will appear on the applicable file as:

NPI	First Name	Last Name	Effective Date	End Date	Opt-out Flag
123456789	John	Smith	11/01/2014	12/15/2014	N

Example 2 - Dr. Mary Jones submits an affidavit to opt-out of Medicare, effective December 1, 2014. Since she has opted out after the generation of the test file, her effective date will display as December 1, 2014. After the 2 year opt-out period expires, Dr. Jones decides she wants to enroll in Medicare to bill, order, and certify, or to write prescriptions. The enrollment application is received on January 31, 2017, and the effective date issued is January 1, 2017. Dr. Jones will display on the applicable file as:

NPI	First Name	Last Name	Effective Date	End Date	Opt-out Flag
987654321	Mary	Jones	12/01/2014	12/01/2016	Y
987654321	Mary	Jones	01/01/2017		N

After the enforcement date of February 1, 2017, the applicable effective dates on the file will be adjusted to February 1, 2017, and it will no longer be considered a test file. All inactive periods prior to February 1, 2017, will be removed from the file and it will only

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contain active and inactive enrollment or opt-out periods as of February 1, 2017, and after. The file will continue to be generated every two weeks, with a purposeful goal of providing updates twice a week by the date of enforcement. Part D sponsors may utilize the file to determine a prescriber's Medicare enrollment or opt-out status when processing Part D pharmacy claims. The file will not validate the provider's ability to prescribe under applicable laws. Please submit questions or issues encountered in accessing the file to providerenrollment@cms.hhs.gov.

Additional Information

For more information on the enrollment requirements, visit <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html> on the CMS website. If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

For a list of Frequency Asked Questions (FAQs) refer to http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/CMS-4159_FAQs.pdf.

Document History

Date of Change	Description
November 16, 2016	The article was revised to show a phased approach to enforcement that will begin in the second calendar quarter of 2017 and end with full implementation and enforcement of the Part D prescriber enforcement requirement on January 1, 2019.
April 18, 2016	The article was revised to amend additional dates in the article to reflect the delayed enforcement date of February 1, 2017.
April 7, 2016	The article was revised to communicate changes to and the delayed enforcement of the Part D prescriber enrollment requirement until February 1, 2017, and to provide clarifying information regarding the enrollment process.
December 5, 2014	The article was revised to add language to emphasize that form CMS-8550 is appropriate for use by prescribers.
October 20, 2015	The article was revised to communicate changes to and the delayed enforcement of the Part D prescriber enrollment requirement until June 1, 2016, and to provide clarifying information regarding the enrollment process.

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