DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

MEDICARE ENROLLMENT & APPEALS GROUP

DATE: October 18, 2016

TO: All Medicare Advantage Organizations and Prescription Drug Plan Sponsors

FROM: Michael Crochunis
Acting Director

SUBJECT: Guidance on Outreach for Information to Support Coverage Decisions

This memorandum provides clarifying guidance related to Medicare Advantage Organizations (MAOs) and Part D Sponsors requesting information (e.g., clinical documentation) from providers and prescribers when adjudicating coverage decisions. This guidance was developed as a result of repeated audit findings that plans are not conducting sufficient outreach to obtain the information needed to make an informed coverage decision, resulting in unnecessary coverage denials, increased appeals volume, and potential access delays for beneficiaries.

The draft 2016 Call Letter solicited feedback from stakeholders on the value of CMS developing guidance on what constitutes reasonable outreach by plans. Commenters generally supported the concept of clarifying parameters about what constitutes reasonable plan outreach. As a result of this feedback, the final 2016 Call Letter noted that CMS would develop sub-regulatory guidance on what constitutes appropriate outreach; this was reiterated in the final 2017 Call Letter. The guidance in this memorandum supersedes any conflicting guidance in the existing versions of Chapter 13 of the *Medicare Managed Care Manual* and Chapter 18 of the *Medicare Prescription Drug Benefit Manual*. Those chapters will be revised to be consistent with this guidance. Until the complete revised versions of Chapter 13 and Chapter 18 are released, the guidance included in this memorandum will be posted and publicly available on the MA and Part D appeals webpages on CMS.gov.

There are separate parameters for expedited and standard requests because what is reasonable in each scenario is likely to be different. The guidance also addresses the number and timing of the attempts made to contact a provider, as well as potential method(s) of contact and the content of messaging to the provider when information is requested.

MEDICARE ADVANTAGE ORGANIZATIONS

The following guidance provides additional detail on CMS' expectations for MAOs. Unless otherwise noted, this guidance applies to situations that involve both contracted and non-contracted providers.

When an MAO does not have all of the information it needs to make a coverage decision, the MAO must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's provider. MAOs are required to conduct outreach within the applicable adjudication timeframe and to document their efforts in accordance with the procedures set forth below. Operational policies and procedures for communicating with providers and requesting information should be designed to satisfy the requirement that pre-service decisions must be issued as expeditiously as the enrollee's health condition requires. See §50.2.1 of Chapter 13 for additional information on the medical exigency standard.

While this section sets forth guidelines for requesting information to support coverage decisions, the sufficiency of the plan's outreach efforts are contingent upon the facts and circumstances of each case. As part of its required organization determination and appeals procedures, MAOs must have procedures in place for requesting and obtaining information necessary for making timely and appropriate decisions. Pursuant to 42 CFR §422.562(a)(4), the plan's medical director should be involved in the development and oversight of such policies and procedures to ensure the appropriateness of the plan's clinical decision-making. Additionally, 42 CFR §422.562(a)(3) states that if an MAO delegates any of its responsibilities for making or reviewing organization determinations, the plan is responsible for ensuring that delegated entities adhere to appropriate procedures.

Documenting Requests for Information

An MAO must conduct a full and meaningful review of an organization determination or reconsideration request. The plan is expected to make reasonable efforts to gather all of the information needed to make substantive and accurate decisions as early in the coverage process as possible. MAOs must document all requests for information and maintain that documentation within the case file. The MAO must clearly identify the records, information, and documents it needs when requesting information from a provider. If the coverage request is made by a contracted provider on behalf of the enrollee, and the provider does not respond to the MAO's requests for information, a plan physician should conduct the outreach to the contracted provider. Contract terms between MAOs and their contract providers are expected to properly incentivize contract providers to produce requested clinical records and other needed information in a timely manner. Documentation should include the following:

- A specific description of the required information;
- The name, phone number, fax number, e-mail, and/or mailing address, as applicable, for the point of contact at the plan; and
- The date and time of each request, documented by date and time stamps on copies of a written request, call record, facsimile transmission, or e-mail. Call records should include specific information about who was contacted, what was discussed/requested, and what information was obtained by the plan.

If the MAO does not obtain the requested information, it must make a decision within the applicable timeframe based on the available clinical information. Extensions to the applicable

adjudication timeframe are permitted, as long as the extension meets the requirements at 42 CFR §§422.568(b)(1), 422.572(b)(1), and 422.590(e)(1), as appropriate. Unless the extension has been requested by the enrollee, the extension must be in the enrollee's interest and either for purposes of requesting information from a non-contract provider that is necessary to approve the request, or because of extraordinary or exigent circumstances. If the plan issues an adverse decision due to the inability to obtain the information needed to approve coverage, the plan should clearly identify that basis and the necessary information in the written denial notice.

Standard Organization Determinations

For all standard organization determination requests, reasonable and diligent efforts to obtain missing information include a minimum of three attempts with requests made, when possible, during normal business hours in the provider's time zone.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail; and/or
- Standard or overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating MAO compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes are considered the date/time of the request to the provider for the information. Requests made by telephone should be documented with the date and time of the call.

The first request for information should be made within two calendar days of receipt of the coverage request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the provider and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the necessary information. Based on the contractual relationship between a plan and its contracted providers, CMS expects that plans will be able to obtain requested documentation from contracted providers in a reliable and timely manner.

Expedited Organization Determinations

For expedited organization determination requests, reasonable and diligent efforts to obtain information include a minimum of three attempts. When possible, attempts should be made during normal business hours in the provider's time zone. Reasonable and diligent attempts to meet the 72-hour decision-making timeframe on an expedited organization determination begin with making the first outreach attempt to the treating provider upon receipt of the coverage request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the provider and receiving the information.

Organization determinations are subject to the expedited timeframe when the enrollee has not yet obtained the item or service and (1) the plan agrees to the enrollee's request to expedite the determination, or (2) the provider has indicated that applying the standard timeframe could seriously jeopardize the enrollee's life or health. CMS expects MAOs, with their medical directors, to design their outreach policies for expedited organization determinations to reflect the immediate need for access to critically needed items and services, including consideration of how the outreach is conducted and who is making the outreach attempts.

What is reasonable will be based upon the facts and circumstances of the case, including the day/time the plan received the expedited request. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information. Based on the contractual relationship between a plan and its contracted providers, CMS expects that plans will be able to obtain requested documentation from contracted providers in a reliable and timely manner.

Methods of outreach can include:

- Telephone;
- Fax;
- E-mail; and/or
- Overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating MAO compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes are considered the date/time of the request to the provider for the information. Requests made by telephone should be documented with the date and time of the call.

Standard Reconsiderations

For all standard reconsideration requests, reasonable and diligent efforts to obtain information include a minimum of three attempts with requests made during normal business hours in the provider's time zone.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail, and/or
- Standard or overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating MAO compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes are considered the date/time of the request to the provider for the information. Requests made by telephone should be documented with the date and time of the call.

The first request for information should be made within four (4) calendar days of receipt of the appeal request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the provider and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information. Based on the contractual relationship between a plan and its contracted providers, CMS expects that plans will be able to obtain requested documentation from contracted providers in a reliable and timely manner.

When adjudicating reconsiderations, if the plan expects to uphold its initial adverse determination based on lack of medical necessity because the plan needs clinical information from the provider to approve coverage, the physician making the reconsideration should attempt to communicate with the requesting provider about the request before the plan issues its decision.

Expedited Reconsiderations

For expedited requests, reasonable and diligent efforts to obtain information include a minimum of three attempts with requests made, when possible, during normal business hours in the provider's time zone. Reconsiderations are subject to the expedited timeframe when the enrollee has not yet obtained the item or service and (1) the plan agrees to the enrollee's request to expedite the reconsideration, or (2) the provider has indicated that applying the standard timeframe could seriously jeopardize the enrollee's life or health. CMS expects MAOs, with their medical directors, to design their outreach policies for expedited reconsiderations to reflect the immediate need for access to critically needed items and services, including consideration of how the outreach is conducted and who is making the outreach attempts.

The first outreach attempt should be made upon receipt of the appeal request in light of the limited time frame for making the reconsideration. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the provider and receiving the information. What is reasonable will be based upon the facts and circumstances of the case, including the day/time the plan received the expedited request. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information. Based on the contractual relationship between a plan and its contracted providers, CMS expects that plans will be able to obtain requested documentation from contracted providers in a reliable and timely manner.

Methods of outreach can include:

- Telephone;
- Fax;
- E-mail; and/or
- Overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating MAO compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes are

considered the date/time of the request to the provider for the information. Requests made by telephone should be documented with the date and time of the call.

PART D SPONSORS

The following guidance provides additional detail on CMS' expectations for Part D sponsors.

When a Part D sponsor does not have all of the information it needs to make a coverage decision, the plan must make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the enrollee's prescriber. Plans are required to conduct outreach within the applicable adjudication timeframe and to document their efforts in accordance with the procedures set forth below. Plan operational policies and procedures for communicating with prescribers and requesting information should be designed to satisfy the requirement that coverage decisions must be issued as expeditiously as the enrollee's health condition requires. See section 50.2.1 of Chapter 18 of the Medicare Prescription Drug Benefit Manual for additional information on the medical exigency standard.

While this section sets forth guidelines for requesting information to support coverage decisions, the sufficiency of the plan's outreach efforts are contingent upon the facts and circumstances of each case. As part of its required coverage determination and appeals procedures, Part D sponsors must have procedures in place for requesting and obtaining information necessary for making timely and appropriate decisions. Pursuant to 42 CFR §423.562(a)(5), the plan's medical director should be involved in the development and oversight of such policies and procedures to ensure the appropriateness of the plan's clinical decision-making. Additionally, 42 CFR §423.562(a)(4) states that if a Part D sponsor delegates any of its responsibilities for making or reviewing coverage determinations, the sponsor is responsible for ensuring that delegated entities adhere to appropriate procedures.

Note regarding MA-PD enrollees: When adjudicating requests for Part D coverage for beneficiaries who are enrolled in MA-PD plans, CMS expects the plan to leverage its contractual relationship when the request involves the need for information from a contracted provider. Contract terms between MAOs and their contract providers are expected to properly incentivize contract providers to produce requested clinical records and other needed information in a timely manner. This expectation extends to all Medicare benefits offered under the plan's contract, including Part D benefits. If the contracted provider does not respond to requests for information and/or the request is made by a contracted provider on behalf of the enrollee, a plan physician should be conducting the outreach to the contracted provider.

Documenting Requests for Information

A Part D sponsor must conduct a full and meaningful review of coverage determination and redetermination requests. The sponsor is expected to make reasonable efforts to gather all of the information needed to make substantive and accurate decisions as early in the coverage process as possible. Part D sponsors must document all requests for information and maintain that documentation within the case file. The plan must clearly identify the records, information and documents needed. The plan's documentation should include the following:

- A specific description of the required information;
- The name, phone number, fax number, e-mail and/or mailing address, as applicable, for the point of contact at the plan; and
- The date and time of each request, documented by date and time stamps on copies of a written request, call record, facsimile transmission or e-mail. Call records should include specific information about who was contacted, what was discussed/requested, and what information was obtained by the plan.

If the Part D sponsor does not obtain the information, it must make a decision within the applicable timeframe based on the available information. If the plan issues an adverse decision due to the inability to obtain medical information needed to approve coverage, the plan should clearly identify that basis and the necessary information in the written denial notice.

Coverage Determinations – Requests for Payment

For all reimbursement requests at the coverage determination level that require information from the prescriber (e.g., the drug is subject to prior authorization and clinical information is missing or a prescriber's supporting statement for an exception is needed), reasonable and diligent efforts to obtain information include a minimum of three attempts.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail; and/or
- Standard or overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating Part D Sponsor compliance with procedures for making coverage decisions. The date/time of the postmark or the timestamp on e-mails and faxes is considered the date/time of the request to the prescriber for the information. Requests made by telephone should be documented with the date and time of the call.

The requests for information should be made in a manner that increases the likelihood of making contact with the prescriber and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information.

Standard Coverage Determinations – Requests for Benefits

For all standard coverage determination requests for benefits, reasonable and diligent efforts to obtain additional information include a minimum of three attempts with the requests made, when possible, during normal business hours in the prescriber's time zone.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail; and/or
- Overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating Part D Sponsor compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes is considered the date/time of the request to the prescriber for the information. Requests made by telephone should be documented with the date and time of the call.

The first request for information should be made within twenty-four (24) hours of receipt of the coverage request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the prescriber and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information.

Expedited Coverage Determinations

For expedited coverage determination requests, reasonable and diligent efforts to obtain information include a minimum of three attempts. When possible, attempts should be made during normal business hours in the prescriber's time zone. However, given the limited timeframe for obtaining information and issuing a determination for an expedited coverage determination, outreach must not be limited to business hours.

Coverage determinations are subject to the expedited timeframe when the enrollee has not yet obtained the drug and (1) the plan agrees to the enrollee's request to expedite the determination because it has determined that applying the standard timeframe could seriously jeopardize the enrollee's life or health, or (2) the prescriber has indicated that applying the standard timeframe could seriously jeopardize the enrollee's life or health. CMS expects Part D sponsors, with their medical directors, to design their outreach policies for expedited coverage determinations to reflect the immediate need for access to critically needed drug therapy, including consideration of how the outreach is conducted and who is making the outreach attempts.

The first outreach attempt should be made upon receipt of the coverage request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the prescriber and receiving the information. What is reasonable will be based upon the facts

and circumstances of the case, including the day/time the plan received the expedited request. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information.

Methods of outreach can include:

- Telephone;
- Fax; and/or
- E-mail.

Recordkeeping is essential for demonstrating Part D Sponsor compliance with procedures for making coverage decisions. The timestamp on an e-mail or fax is considered the date/time of the request. Requests made by telephone should be documented with the date and time of the call.

Standard Redeterminations

For all standard redetermination requests, reasonable and diligent efforts to obtain information include a minimum of three attempts with requests made, when possible, during normal business hours in the prescriber's time zone.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail; and/or
- Overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating Part D Sponsor compliance with procedures for making coverage decisions. The date/time of the postmark or the timestamp on e-mails and faxes is considered the date/time of the request to the prescriber for the information. Requests made by telephone should be documented with the date and time of the call.

For standard redetermination requests, the first request for information should be made within two calendar days of receipt of the appeal request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the prescriber and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information.

When adjudicating redeterminations, if the plan expects to uphold its initial adverse decision based on lack of medical necessity because the plan needs information from the prescriber to approve coverage, the physician making the redetermination should attempt to communicate with the prescriber about the request before issuing the determination.

Expedited Redeterminations

For all expedited redetermination requests, reasonable and diligent efforts to obtain information include a minimum of three attempts made, when possible, during normal business hours in the prescriber's time zone. Redeterminations are subject to the expedited timeframe when the enrollee has not yet obtained the drug and (1) the plan agrees to the enrollee's request to expedite the determination because it has determined that applying the standard timeframe could seriously jeopardize the enrollee's life or health, or (2) the prescriber has indicated that applying the standard timeframe could seriously jeopardize the enrollee's life or health. CMS expects Part D sponsors, with their medical directors, to design their outreach policies for expedited coverage determinations to reflect the immediate need for access to critically needed drug therapy, including consideration of how the outreach is conducted and who is making the outreach attempts.

Methods for requesting information can include:

- Telephone;
- Fax;
- E-mail; and/or
- Overnight mail with certified return receipt.

Recordkeeping is essential for demonstrating Part D Sponsor compliance with procedures for making coverage decisions. The date/time of the postmark or timestamp on e-mails and faxes is considered the date/time of the request to the prescriber for the information. Requests made by telephone should be documented with the date and time of the call.

The first request for information should be made upon receipt of the appeal request. CMS expects subsequent requests to be timed in a manner that increases the likelihood of making contact with the prescriber and receiving the information. If the sufficiency of the plan's outreach efforts in a given case are subject to review, consideration will also be given to whether the plan used multiple means of communication (e.g., phone, fax, e-mail) in an effort to obtain the information.

When adjudicating expedited redeterminations, if the plan expects to uphold its initial adverse decision based on lack of medical necessity because the plan needs information from the prescriber to approve coverage, the physician making the redetermination should attempt to communicate with the prescriber about the request before issuing the determination.

Questions about this guidance should be directed to the following resource mailboxes:

- Medicare Advantage: Part_C_Appeals@cms.hhs.gov
- Part D: PartD_Appeals@cms.hhs.gov
- CMS audits: part_c_part_d_audit@cms.hhs.gov