ATTACHMENT VII

Part C Organization Determinations, Appeals, and Grievances (ODAG) Audit Process and Universe Request

Purpose: To evaluate a Medicare plan's performance in the four (4) areas outlined below related to organization determinations, appeals, and grievances. The Centers for Medicare & Medicaid Services will perform its audit activities using these instructions (unless otherwise noted).

Review Period: Three (3) month period preceding the date of the audit engagement letter (Month, Day, Year through Month, Day, Year) CMS reserves the right to expand the review period to ensure a sufficient universe size.

Note: The plan is expected to provide accurate and timely universe submissions. In addition, the plan is expected to present their supporting documentation during the audit and upload it to the secure site using the designated naming convention within the timeframe specified by the reviewers. If the plan fails to provide accurate and timely universe submissions or fails to submit the supporting documentation using the designated naming convention and within the timeframe specified by the reviewers, CMS will document this as an observation in the plan's program audit report.

I. Effectuation Timeliness - Organization Determinations and Appeals (ODA)

1. Select Universe and submit to CMS: The plan is expected to provide accurate and timely universe submissions. In addition, they will pull a universe consisting of all pre-service and payment organization determinations and reconsiderations decisions which were approved (i.e., favorable to the enrollee) during the review period. The date of the favorable determination should fall within the review period specified above.

Submit Universes in Attachment VII-A1 (**Effectuation Timeliness (ET)**). The Plan will designate the type of case (Pre-service, Payment, Reconsideration, or IRE-ALJ MAC) in the designated column of the universe template. The Plan should submit its universes in whole and not separately for each contract. If the file is too large for Excel, a CSV or a text file is acceptable.

Note: The dates of the favorable determinations and the IRE, ALJ and MAC reversals (overturns) should fall within the review period specified above.

The universe should consist of the following:

1.1. Pre-service organization determinations consisting of decisions to approve medical care/services before the services are provided to enrollees.

1.1.1. Exclude concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, and requests for extensions of previously approved services.

1.2. Payment organization determinations consisting of non-contracted provider paid claims. A claim consists of one or more service line items. This universe should only include one record for the entire claim. The entire claim must be paid.

1.2.1. Exclude duplicate claims and payment adjustments to claims.

1.3. Reconsiderations in which the original denial of an organization determination of either pre-service or payment was overturned in whole by the plan.

1.4. Reconsiderations overturned by the IRE, ALJ, or MAC. (**Note:** This universe is the same as the universe described in Section II, 1.4).

2. Timeliness test: During the pre-audit period (after universes are received from the Sponsor but prior to the live audit review), CMS will perform an analysis of the submitted universe to determine the percentage timely for each of the following categories:

2.1. Decision-making timeliness for:
- 2.1.1. Standard organization determinations
- 2.1.2. Expedited organization determinations
- 2.1.3. Standard reconsideration requests
- 2.1.4. Expedited reconsideration requests

2.2. Notification timeliness for:
- 2.2.1. Standard organization determinations
- 2.2.2. Expedited organization determinations
- 2.2.3. Standard reconsideration requests
- 2.2.4. Expedited reconsideration requests

2.3. Effectuation timeliness:
- 2.3.1. Standard organization determinations
- 2.3.2. Expedited organization determinations
- 2.3.3. Standard reconsideration requests
- 2.3.4. Expedited reconsideration requests

The audit team will record the percentage of cases that were timely for each of the metrics listed above. CMS will set three timeliness thresholds for each of the metrics above and sponsors will be scored accordingly. CMS will determine an acceptable threshold for each metric, in which a sponsor above the threshold will generally not be cited a condition. CMS will also set a second threshold for each metric, in which a sponsor falling below this threshold will be cited for a corrective action required (CAR) for unmet timeliness metrics. CMS will set a third threshold for each metric, in which a sponsor falling below this threshold will be cited an immediate corrective action (ICAR) for unmet timeliness metrics.

3. Select 10 Cases: CMS will randomly select up to 10 random cases from these respective universe categories:
- favorable organization determination cases;
- favorable reconsiderations cases; and
- cases overturned by the IRE, ALJ or MAC.

4. Obtain Evidence: During the live review portion of the audit CMS will verify the accuracy of the dates provided in the universe submission.
Obtain evidence from sponsor for each case selected to review for timely notification and effectuation. For each case, the plan must produce all relevant documentation including, **but not limited to**:
- Original pre-service or payment (i.e., claim) or reconsideration request.
- Letters, emails or documentation confirming the plan's receipt of the request.

- Notices, letters, or other documentation showing the plan requested additional information (if applicable) from the requesting provider/physician, including date, time, and type of communication.
- All supplemental information submitted by the requesting provider/physician or enrollee, including documentation showing when information was received by the plan.
- Notices/letters to enrollees or reports or other logs that show when enrollee or provider/physician was notified of the decision and effectuation was made in the plan's systems.
- If applicable, all documentation to support the plan's decision to process an expedited request under the standard timeframe, including any pertinent medical documentation, and any associated notices provided to the enrollee and the requesting provider/physician.

5. Apply Compliance Standard: Apply the following test to each of the 10 cases. For a case to receive a score of "pass", the case must present evidence to favorably address the following question:

5.1. Are the dates observed during live audit consistent with the universe submission?

Note: The integrity of the universe will be questioned if the timeliness metrics on 6 or more cases observed during live audit review do not match the metrics provided in the universe. If this occurs CMS will request a new universe to test timeliness. Sponsors providing misleading information to CMS will be referred to the Division of Compliance and Enforcement for a civil monetary penalty. 42 CFR 422.752(c)

6. Sample Case Results: CMS will test each of the 10 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

II. Appropriateness of Clinical Decision-Making & Compliance with ODA Processing Requirements

1. Select Universe and submit to CMS: Plan will pull a universe consisting of: all organization determinations and reconsiderations that were denied in whole or in part (i.e. unfavorable to the enrollee) during the review period, including those that were untimely and auto-forwarded to the IRE; and all IRE, ALJ, or MAC reconsiderations that reversed/overturned the plan's denial in whole or in part (favorable to the enrollee) during the review period.

Note: The dates of the unfavorable determinations and the IRE, ALJ and MAC reversals (overturns) should fall within the review period specified above. The universe should consist of the following:

1.1. Pre-service organization determinations consisting of decisions to deny medical care/services before they are provided to enrollees.

1.1.1. Exclude concurrent review for inpatient hospital and SNF services, post-service reviews, notification of admission, and requests for extensions of previously approved services.

1.2. Payment organization determinations consisting of contracted or non-contracted provider denied claims. A claim consists of one or more service line items. If any line item is denied, the entire claim is considered adverse. This universe should only include one record for the entire claim.

1.2.1. Exclude claims that denied as duplicate; claims that denied for invalid billing codes; denied claims for beneficiaries who are not enrolled on the date of service; and denied due to recoupment of payment.

1.3. Reconsiderations in which the original denial of an organization determination (pre-service or payment) was upheld in whole or in part by the plan.

1.4. Reconsiderations overturned by the IRE, ALJ, or MAC.

Submit Universe in Attachment VII-A2 (**Clinical Decision Making (CDM)**). The Plan will designate the type of case (Pre-service, Payment, Reconsideration, or IRE-ALJ MAC) in the designated column of the universe template. The Plan should submit its universes in whole and not separately for each contract. If the file is too large for Excel, a CSV or a text file is acceptable.

2. Timeliness test: During the pre-audit period (after universes are received from the Sponsor but prior to the live audit review) CMS will perform an analysis of the submitted universe to determine the percentage timely for each of the following categories:

2.1. Decision-making timeliness for:

2.1.1. Standard organization determinations

2.1.2. Expedited organization determinations

2.1.3. Standard reconsideration requests

2.1.4. Expedited reconsideration requests

2.2. Notification timeliness for:

2.2.1. Standard organization determinations

2.2.2. Expedited organization determinations

2.2.3. Standard reconsideration requests

2.2.4. Expedited reconsideration requests

The audit team will record the percentage of cases that were timely for each of the metrics listed above. CMS will set three timeliness thresholds for each of the metrics above and sponsors will be scored accordingly. CMS will determine an acceptable threshold for each metric, in which a sponsor above the threshold will generally not be cited a condition. CMS will also set a second threshold for each metric, in which a sponsor falling below this threshold will be cited for a corrective action required (CAR) for unmet timeliness metrics. CMS will set a third threshold for each metric, in which a sponsor falling below this threshold will be cited an immediate corrective action (ICAR) for unmet timeliness metrics.

3. Select 30 Cases: In sampling, CMS will ensure the 30 cases appear clinically significant. The sample will represent various medical services (ER services, outpatient hospital, inpatient hospital, urgent care). CMS will select a targeted sample of 30 cases from the universe categories as follows:

- 10 adverse organization determination cases;
- 10 adverse reconsideration cases; and
- 10 cases overturned by the IRE, ALJ, or MAC.

If there are not enough reconsideration, IRE, ALJ, or MAC cases, CMS will increase the number of organization determinations cases to obtain a total sample size of 30.

4. Obtain Evidence (Case Files): During the live review portion of the audit CMS will verify the accuracy of the dates provided in the universe submission. CMS will review for proper notification and clinical appropriateness of the decision and for timely effectuation by the plan of the IRE, ALJ or MAC overturns. For each case, the plan must produce all relevant documentation including, **but not limited to**:

- Original pre-service or payment (i.e., claim) or reconsideration request.
- All notices, letters, or other documentation showing the plan requested additional information (if necessary) from the provider/physician, including date, time and type of communication.
- All supplemental information submitted by the provider/physician, including documentation showing when information was received by plan.
- Documentation showing the plan's rationale for the decision, including any standard operating procedures or standard decision trees used by clinical personnel, internal communication(s); and reference to CMS Guidance, Federal Regulations, and plan documents (e.g., EOC, SB, NCDs, LCDs), as applicable.
- All notices, letters, and communications to the enrollee (and provider/physician, if applicable) demonstrating when notification was made.
- For cases that were auto-forwarded to the IRE, the case file should include documentation showing when the case was forwarded and when the enrollee was notified that the case was sent to the IRE.

5. Apply Applicable Compliance Standard: Apply the applicable test to the relevant 30 sampled cases. For an initial organization determination case to receive a score of "pass," the case must present evidence to favorably address questions 5.1.2. through 5.1.4. For a reconsideration case to receive a score of "pass" the case must present evidence to favorably address questions 5.2.1 through 5.2.4 and favorably address question 5.2.5 or 5..6.

5.1. Initial organization determination requests that were partially or fully denied for lack of medical necessity:

5.1.1. Was appropriate notification provided to the enrollee (or representative) and provider/physician, if applicable?

5.1.2. Was the request reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise including knowledge of Medicare coverage criteria?

5.1.3. Did the plan appropriately consider clinical information and comply with CMS coverage and notification requirements?

5.1.4. Did the enrollee get a clinically equivalent or alternate service?

5.2. Reconsiderations where the initial organization determination was denied for lack of medical necessity:

5.2.1. Was appropriate notification provided to the enrollee (or representative) and provider/physician, if applicable?

5.2.2. Was the reconsideration reviewed by a *different* physician with expertise in the field of medicine that is appropriate for the services at issue?

5.2.3. Did the plan appropriately consider clinical information and comply with CMS coverage and notification requirements?

5.2.4. If care or services were provided or referred by a contracted provider, and if so, was the member held harmless? or

5.2.5. If the plan did not meet the decision making timeframe, did the plan auto-forward to the IRE properly and within the required timeframe?

5.2.6. Did the enrollee get a clinically equivalent or alternate service?

5.3. Are the dates and times observed during live audit consistent with the universe submission?

Note: The integrity of the universe will be questioned if the timeliness metrics on 6 or more cases observed during live audit review do not match the metrics provided in the universe. If this occurs CMS will request a new universe to test timeliness. Sponsors providing misleading information to CMS will be referred to the Division of Compliance and Enforcement for a civil monetary penalty. 42 CFR 422.752(c)

6. Sample Case Results: CMS will test each of the 30 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

III. Grievances

1. Select Universe and submit to CMS: Plan will pull a universe consisting of all grievances received (e.g., written correspondence, calls received by customer service representatives, etc.) during the review period.

Submit Universe in Attachment VII-A3 (**Grievances**). The Plan should submit its universes in whole and not separately for each contract. If the file is too large for Excel, a CSV or a text file is acceptable.

2. Select 15 Cases: CMS will select a targeted sample of 15 grievances from the universe. The sample will consist of oral and written grievances.

3. Obtain Evidence: CMS will review to determine timeliness, appropriate classification, notification and outcome. For each case, plan must produce all relevant documentation for including, but not limited to:

- Original grievance
- Documentation showing when grievance was received.
- Documentation explaining the issue.
- Documentation showing the Plan's investigation follow-up steps, and description of the final grievance outcome.

3.1. For quality of care grievances: provide documentation that supports that an investigation and appropriate follow up took place.

3.1.1. Include all notices, letters, and beneficiary communications demonstrating when notification of the final grievance outcome was made.

4. Apply Compliance Standard: Apply the following test to each of the 15 cases. For a case to receive a score of "pass", the case must present evidence to favorably address all of the following questions:

4.1. Was the case correctly categorized as a grievance, and if not, was it transferred to the appropriate process?

4.2. Was the enrollee notified of the disposition timely?; and

4.3. Did the grievance notification appropriately address all issues raised in the complaint?

5. Sample Case Results: CMS will test each of the 15 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.

IV. Dismissals

1. Select Universe and submit to CMS: Plan will pull a universe consisting of all plan-level reconsideration requests (both pre-service and request for payment) that were dismissed due to missing Waiver of Liability (WoL), missing CMS-1696 Appointment of Representative (AoR) (or other conforming instrument) or other procedural defect during the review period. The universe of dismissals should include all dismissals which were appealed to and overturned by the IRE.

Submit Universe in Attachment VII-A (**Dismissal Tab**). The Plan will designate the type of Dismissal (Pre-service or Payment) in the designated column of the template. The Plan should submit its universes in whole and not separately for each contract. If the file is too large for Excel, a CSV or a text file is acceptable.

2. Select 20 Cases: CMS will select a targeted sample of 20 plan-level requests for dismissal as follows:

- 10 pre-service dismissals, 5 of which were appealed to the IRE (if there are not 5 pre-service dismissals that were appealed to the IRE in the universe, please include all cases that were dismissed).
- 10 payment dismissals, 5 of which were appealed to the IRE (if there are not 5 payment dismissals that were appealed to the IRE in the universe, please include all cases that were dismissed).

3. Obtain Evidence: CMS will review to determine if the:

- Plan made reasonable efforts to obtain an Appointment of Representative (AOR) (or other conforming instrument) or Waiver of Liability (WoL).
- Plan sent a written notice of the dismissal to the parties at their last known addresses within the applicable adjudication timeframe pursuant to the requirements of 42 CFR Part 422, Subpart M
- Dismissal notice states the reason for the dismissal.

- Dismissal notice explains the right to request IRE review of the dismissal within 60 calendar days after receipt of the written notice of the plan's dismissal.
- If applicable, plan assembled and forwarded the case file to the IRE within 24 hours of receiving the IRE's case file request.
- If applicable, did the IRE remand the case back to the plan?

For each case, plan must produce all relevant documentation including, but not limited to:

- Original pre-service or payment (i.e., claim) or reconsideration request.
- Initial organization determination.
- Letters, emails or documentation confirming the plan's receipt of the request.
- Notices, letters, or other documentation showing the plan requested additional information (i.e., the WoL or AOR (or other conforming instrument)) from the requesting provider/physician or purported representative, including date, time and type of communication.
- All supplemental information submitted by the requesting provider/physician or representative, including documentation showing when the information was received by the plan.
- Written notice of dismissal.
- If applicable, case file sent to the IRE (including documentation of the time sent).

4. Apply Compliance Standard: Apply the following test to each applicable case:

4.1. Pre-service dismissal cases: For a case to receive a score of "pass," the case must present evidence to favorably address all of the following questions:

4.1.1. Did the plan make a reasonable effort to obtain the AOR (or other conforming instrument) and document those efforts in the case file?

4.1.2. Did the plan send a written notice of the dismissal to the parties at their last known addresses within the applicable adjudication timeframe pursuant to the requirements of 42 CFR Part 422, Subpart M?

4.1.3. Did the dismissal notice state the reason for the dismissal?

4.1.4. Did the dismissal notice explain the right to request IRE review of the dismissal within 60 calendar days after receipt of the written notice of the plan's dismissal?

4.1.5. If applicable, did the plan assemble and forward the case file to the IRE within 24 hours of receiving the IRE's case file request?

4.2. Payment dismissal cases: For a case to receive a score of "pass", the case must present evidence to favorably address all of the following questions:

4.2.1. Did the plan make a reasonable effort to obtain the AOR (or other conforming instrument) or WoL and document those efforts in the case file?

4.2.2. Did the plan send a written notice of the dismissal to the parties at their last known addresses within the applicable adjudication timeframe pursuant to the requirements of 42 CFR Part 422, Subpart M?

4.2.3. Did the dismissal notice state the reason for the dismissal?

4.2.4. Did the dismissal notice explain the right to request IRE review of the dismissal within 60 calendar days after receipt of the written notice of the plan's dismissal?

4.2.5. If applicable, did the plan assemble and forward the case file to the IRE within 24 hours of receiving the IRE's case file request?

5. Sample Case Results: CMS will test each of the 20 cases. If CMS requirements are not met, a sample case fails and a condition (finding) is documented. If CMS requirements are met, a sample case passes and no conditions (findings) are documented.