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

PROGRAM COMPLIANCE AND OVERSIGHT GROUP

October 9, 2012

VIA:
EMAIL (rcostilla@mapfrepr.com)
AND FACSIMILE (787-772-8886)

Raul Costilla
President and Chief Executive Officer
MAPFRE PRAICO Corporation
Urb Tres, Monjitas Industrial
297 Carlos Chardón Avenue
San Juan, PR 00918-1410
Phone: 787-250-6500 Ext. 5373

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug Plan Contract Number: MAPFRE Life Insurance Company (H5821)

Dear Mr. Costilla:

Pursuant to 42 C.F.R. §§ 422.756 and 423.756, the Centers for Medicare & Medicaid Services (CMS) hereby informs MAPFRE PRAICO Corporation (MAPFRE) of its determination to immediately impose intermediate sanctions on the following Medicare Advantage-Prescription Drug Plan (MA-PD) Contract: MAPFRE Life Insurance Company H5821.

These intermediate sanctions will consist of the suspension of the enrollment of Medicare beneficiaries (42 C.F.R. §§ 422.750(a)(1) and 423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. §§ 422.750(a)(3) and 423.750(a)(3)). CMS is imposing these intermediate sanctions immediately, effective October 9, 2012 at 11:59 p.m. EST, pursuant to 42 C.F.R. §§ 422.756(c)(2) and 423.756(c)(2), because it has determined that MAPFRE's conduct poses a serious threat to the health and safety of Medicare beneficiaries. Pursuant to 42 C.F.R. §§ 422.756(c)(3) and 423.756(c)(3), the intermediate marketing and enrollment sanctions will remain in effect until CMS is satisfied that the deficiencies upon which the determination was based have been corrected and are not likely to recur. CMS will provide

MAPFRE with detailed instructions regarding the marketing and enrollment suspension in a separate communication.

CMS has determined that MAPFRE failed to provide its enrollees with services and benefits in accordance with CMS requirements. An MA-PD sponsor's central mission is to provide Medicare enrollees with medical services and prescription drug benefits within a framework of Medicare requirements that provide enrollees with a number of protections.

Summary of Noncompliance

CMS conducted an audit at MAPFRE's San Juan, Puerto Rico offices from August 6, 2012 through August 10, 2012. During the audit, CMS conducted reviews of MAPFRE's operational areas to determine if MAPFRE is following CMS rules, regulations, and guidelines. After conducting an extensive review, CMS auditors concluded that MAPFRE substantially failed to comply with CMS requirements regarding the processing of Part C and Part D grievances, organization/coverage determinations, and Part C and Part D appeals. 42 C.F.R. Part 422, Subparts C, F, K and M and 42 C.F.R. 423, Subparts C, K and M. CMS found that MAPFRE's failures in these areas were widespread and systemic. Violations in these areas can result in enrollees experiencing delays or denials in receiving covered medical services or prescription drugs, and increased out of pocket costs.

Part C and Part D Grievance, Organization Determination, Coverage Determination and Part C and Part D Appeal Requirements

Medicare enrollees have the right to contact their plan sponsor to express general dissatisfaction with the operations, activities, or behavior of the plan sponsor or to make a specific complaint about the denial of coverage for drugs or services to which the enrollee believes he or she is entitled. Sponsors are required to classify general complaints about services, benefits, or the sponsor's operations or activities as grievances. 42 C.F.R. §§ 422.564 (a-b) and 423.564 (a-b). Sponsors are required to classify complaints about coverage for drugs or services as organization determinations (Part C – medical services) or coverage determinations (Part D – drug benefits). 42 C.F.R. §§ 422.564 (b), 422.566(b), 423.564(b) and 423.566(b). It is critical for a sponsor to properly classify each complaint as a grievance or an organization/coverage determination or both. Improper classification of an organization or coverage determination denies an enrollee their due process and appeal rights and may delay an enrollee's access to medically necessary or life-sustaining services or drugs.

The enrollee, the enrollee's representative, or the enrollee's treating physician or prescriber may make a request for an organization determination or coverage determination. 42 C.F.R. §§ 422.566(c) and 423.566(c). The first level of review is the organization determination or coverage determination, which is conducted by the plan sponsor, and the point at which beneficiaries or their physicians submit justification for the service or benefit. 42 C.F.R. §§ 422.566(d) and 423.566(d). If the organization or coverage determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. 42 C.F.R. §§ 422.580 and 423.580. The first level of the appeal – called a reconsideration (Part C) or redetermination (Part

D) – is handled by the plan sponsor and must be conducted by a physician who was not involved in the organization determination or coverage determination decision. 42 C.F.R. §§ 422.590(g) and 423.590(f). The second level of appeal is made to an independent review entity (IRE) contracted by CMS. 42 C.F.R. §§ 422.592, 423.600.

There are different decision making timeframes for the review of organization determinations, coverage determinations, and appeals. 42 C.F.R. §§ 422.572, 422.590, 423.572, and 423.590. CMS has a beneficiary protection in place that requires plans to forward coverage determinations and appeals to the IRE when the plan has missed the applicable adjudication timeframe. 42 C.F.R. §§ 422.590(f) and 423.590(e).

Deficiencies Related to Grievances, Organization Determinations, Coverage Determinations and Appeals

CMS identified multiple, serious violations of Part C and Part D requirements in MAPFRE's grievances, organization determinations, coverage determinations and appeals operations. MAPFRE's violations discovered during the audit and through subsequent monitoring include:

Part C

- Failure to process beneficiaries' pre-service requests for medical coverage as organization determinations, in violation of 42 C.F.R. § 422.566(c);
- Failure to process cases as expedited despite a physician's request to do so, in violation of 42 C.F.R. §§ 422.570(c)(2)(ii) and 422.584(c)(2)(ii);
- Insufficient staffing to ensure that enrollees have adequate access to the organization determinations and appeals processes on weekends and holidays, in violation of 42 C.F.R. §§ 422.503(b)(4)(ii) and 422.566(a) and IOM Pub. 100-16, Medicare Managed Care Manual Chapter 3, Section 80.1;
- Failure to conduct appropriate outreach to the requesting provider or treating physician for missing clinical information, in violation of 42 C.F.R. §§ 422.566 and 422.578 and IOM Pub. 100-16, Medicare Managed Care Manual Chapter 13, Sections 50.1 and 70.5;
- Failure to consider applicable Medicare coverage criteria when making medical necessity decisions for organization determinations, in violation of 42 C.F.R. § 422.101(b);
- Consistently charging cost-share amounts that are not in accordance with MAPFRE's Explanation of Coverage (EOC) and/or the approved plan bid, in violation of 42 C.F.R. §§ 422.100(d), 422.262(c), 422.270 and 422.504(g)(1)(ii);
- Substantial failure to ensure that organization determinations and plan reconsiderations were processed and enrollees notified within the required timeframes, in violation of 42 C.F.R. §§ 422.568(b-f), 422.572(a) and 422.590(a-d);
- Substantial failure to issue a Notice of Denial of Medical Coverage or Notice of Denial of Payment, as appropriate, for adverse organization determinations, in violation of 42 C.F.R. §§ 422.568(d-e) and 422.572(a) and (e) and IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Sections 40.2.1 and 50.5; and
- Failure to forward adverse reconsiderations to the IRE for review, in violation of 42 C.F.R. §§ 422.590 (a)(2), 422.590(b)(2) and 422.590(c).

Part D

- Failure of MAPFRE's Medical Director to oversee Part D coverage determinations and appeals effectively, in violation of § 42 C.F.R. 423.562(a)(5). The Medical Director did not demonstrate adequate understanding of Part D requirements during the CMS audit, and was not able to articulate what, if any, role she plays in ensuring the clinical accuracy of coverage determinations and redeterminations involving medical necessity;
- Insufficient staffing to ensure that enrollees have adequate access to the coverage determinations and appeals processes on weekends and holidays, in violation of 42 C.F.R. §§ 423.128(d)(1)(iv), 423.504(b)(4)(ii) and 423.566(a), IOM Pub. 100-18, Prescription Drug Benefit Manual Chapter 3, Section 80.1 and Appendix 5 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 40.2, 50.4, 70.7, and 70.8.1;
- Failure to appropriately categorize and process grievances in accordance with 42 C.F.R. § 423.564 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 20.3;
- Failure to ensure that an appropriate health care professional is reviewing adverse coverage determinations in cases of medical necessity, in violation of 42 C.F.R. § 423.566(d);
- Failure to ensure that an appropriate physician makes decisions for all redetermination requests which are denied for lack of medical necessity, in violation of 42 C.F.R. § 423.590(f)(2) and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 70.6;
- Failure to consider applicable clinical information from prescribers when rendering a decision, in violation of 42 C.F.R. §§ 423.566(a), 423.578(a) and (b) and 423.586, and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1, 30.2.2, 70.7 and 70.8.1;
- Failure to conduct appropriate prescriber outreach before denying coverage requests which contain incomplete clinical information, in violation of 42 C.F.R. §§ 423.566(a) and 423.586 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1, 30.2.2 and 70.5;
- Inappropriately denying drugs for which only a particular use or uses are excluded under Part D without considering the use that was being requested by the prescriber, in violation of 42 C.F.R. §§ 423.120 and 423.578(b) and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 20.2.4;
- Failure to forward untimely coverage determination and appeal cases to the IRE upon expiration of the adjudication timeframe, in violation of 42 C.F.R. §§ 423.568(h), 423.572(d), 423.590(c) and 423.590(e), and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 40.2, 50.6, 70.7.1, 70.8.2, and 70.10;
- Failure to process coverage determinations and appeals within the required timeframes, in violation of 42 C.F.R. §§ 423.568(b), 423.572(a), 423.590(a) and 423.590(d), and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18 of the Medicare Prescription Drug Manual, Sections 30, 40.2 50.4, 70.7, 70.8.1, 130.1 and 130.2;
- Failure to send appropriate denial letters to beneficiaries stating the specific reason(s) for the denial, in violation of 42 C.F.R. §§ 423.568(f-g), 423.572(c)(2) and 423.590(g), and

IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 40.3.4, 50.5, 70.9.1 and 70.9.2; and

- Failure to effectuate decisions in its system appropriately in violation of 42 C.F.R. § 423.578(c) and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 30.2, which requires that approved exceptions be extended through the end of the plan year. Examples: In several cases, the approval for an exception request did not extend through the plan year. In some cases, approvals were entered into the system before the clinician reviewed and approved the determination. Additionally, the plan was approving prescriptions at a specific strength level instead of approving the drug under all strength levels.

Violations of Grievance, Coverage Determination, Organization Determination and Appeal Requirements Create a Serious Threat to Enrollee Health and Safety

CMS is imposing these intermediate sanctions as a result of MAPFRE's failure to provide its enrollees with required coverage determinations, organization determinations, redeterminations, appeals and grievances in conformance with applicable law, the terms of its contract and CMS guidance. As stated above, MAPFRE's failures are so widespread and systemic that MAPFRE enrollees are being denied access to a critical component of Medicare coverage. MAPFRE's enrollees are being denied access to the due process and appeal rights which would safeguard access to all drugs and services to which they are medically and legally entitled.

MAPFRE's seriously deficient administration of its Part C organization determinations, Part D coverage determinations, and Parts C and D appeals and grievances poses a serious threat to the health and safety of MAPFRE's enrollees. When enrollees do not have access to a robust and effective grievances and appeals process, they may be unable to obtain needed, and sometimes life-sustaining, prescription medications and services. CMS is, therefore, compelled to immediately impose marketing and enrollment sanctions.

Despite extensive communication with CMS about these serious compliance issues, MAPFRE has not satisfactorily addressed these serious deficiencies. Accordingly, the circumstances demand the imposition of marketing and enrollment sanctions until the violations can be cured with reasonable assurance that they will not recur.

Compliance Program Deficiencies

In addition to the extensive violations of Part C and D requirements regarding grievance and appeals procedures which create a serious threat to enrollee health and safety, CMS' audit determined that MAPFRE failed to establish and implement an effective compliance program to detect, correct and prevent Medicare program noncompliance and potential fraud, waste and abuse (FWA), as required by 42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi). *See also,* IOM Pub. 100-16 Medicare Managed Care Manual Chapter 21 and IOM pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 9 for additional guidance on the seven required elements of an effective compliance program.

MAPFRE's compliance program violations discovered during the audit and through subsequent monitoring include:

- Failure to provide compliance training upon hire and annually thereafter to its Board members, senior management, and employees, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C);
- Failure to provide fraud, waste and abuse training upon hire and annually thereafter to its Board members, senior management, and employees, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C);
- Failure to establish and implement an effective system for identification of compliance risks, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F);
- Failure to establish and implement a system for monitoring of compliance program effectiveness, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F);
- Failure to establish and implement a system for auditing compliance program effectiveness, in violation of42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F);
- Failure to establish and implement procedures and a system to investigate potential FWA problems as identified in the course of self-evaluations and audits, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 423.504(b)(4)(vi)(G);
- Failure to establish and implement a system to ensure appropriate corrective actions are taken when instances of noncompliance or FWA are identified, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 423.504(b)(4)(vi)(G);
- Failure to establish and implement effective FWA training for its first tier, downstream, and related entities (FDRs) upon contracting and annually thereafter, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C);
- Failure to ensure that compliance and FWA reporting mechanisms are accessible and well-publicized to FDRs, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(D) and 423.504(b)(4)(vi)(D);
- Failure to establish and implement a system for routine monitoring of their FDRs to ensure compliance with CMS regulations, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F); and
- Failure to establish and implement a system for auditing of their FDRs to ensure compliance with CMS regulations, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).

Legal Basis for Immediate Imposition of Marketing and Enrollment Sanctions

CMS has determined that MAPFREs deficiencies, as described in detail herein, provide a sufficient basis for the immediate imposition of intermediate sanctions (42 C.F.R. §§ 422.752(b) and 423.752(b)). CMS has determined that:

- MAPFRE substantially failed to carry out the terms of its MA Organization and Prescription Drug Plan contracts with CMS (42 C.F.R. §§ 422.510(a)(1) and 423.509(a)(1));

- MAPFRE is carrying out its contracts with CMS in a manner that is inconsistent with the effective and efficient implementation of the program (42 C.F.R. §§ 422.510(a)(2) and 423.509(a)(2)); and
- MAPFRE substantially failed to comply with the requirements in 42 C.F.R. Parts 422 and 423 Subpart M related to grievances and appeals (42 C.F.R. §§ 422.510(a)(5) and 423.509(a)(5)).

Further, CMS has determined that MAPFRE's conduct poses a serious threat to the health and safety of its enrollees. Consequently, these sanctions are effective on October 9, 2012, pursuant to the authority provided by 42 C.F.R. §§ 422.756(c)(2) and 423.756(c)(2).

MAPFRE's Notice and Opportunity to Correct

Since the August 2012 audit, MAPFRE has been given repeated notice of its deficiencies and provided with multiple opportunities to correct. On August 15, 2012, CMS sent MAPFRE an Immediate Corrective Action Request in which MAPFRE was given seventy-two (72) hours to implement the corrective actions required. CMS reviewed MAPFRE's corrective action submission and concluded that MAPFRE failed to demonstrate sufficient correction in the time period allotted. CMS then granted MAPFRE an additional opportunity to implement the correction. CMS reviewed MAPFRE's second corrective action submission and concluded that MAPFRE's corrective action plans continue to demonstrate a failure to effectively correct deficiencies.

Corrective Action Steps

As stated above, pursuant to 42 C.F.R. §§ 422.756(c)(3) and 423.756(c)(3), the sanctions will remain in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur. Attached to this notice is a template Corrective Action Plan with instructions for MAPFRE to complete. MAPFRE should submit its Corrective Action Plan to CMS seven (7) calendar days from the date of receipt of this notice, or by October 16, 2012. If MAPFRE needs additional time beyond seven (7) days to submit a corrective action plan contact your enforcement lead.

The Corrective Action Plan will assist MAPFRE in correcting the deficiencies that are the basis for the sanction determination as quickly as possible. The completed document will also guide communications with CMS and serve as a tool for CMS to monitor MAPFRE's progress.

Once MAPFRE has fully implemented its Corrective Action Plan and submitted to CMS an attestation from the MAPFRE's Chief Executive Officer, or most senior official, stating that MAPFRE has corrected the deficiencies that are the basis for the sanction and they are not likely to recur, validation activities will be scheduled by CMS. Validation consists of CMS sending a data and documentation request to MAPFRE, followed by an on-site visit at CMS headquarters, where CMS will examine MAPFRE's live operational systems. Unless otherwise informed, CMS will use the same protocols and templates for validation that are used for the 2012 program audits. The results of validation are used in conjunction with information gathered from

MAPFRE's Corrective Action Plan, issues discovered during routine account management monitoring, and the identification of any additional sanction related issues to determine whether the underlying deficiencies have been corrected and are not likely to recur.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. §§ 422.756(a)(2) and 423.756(a)(2), MAPFRE has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by October 19, 2012. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, or in this case, October 10, 2012. If you choose to submit a rebuttal, please send it to the attention of Gerard J. Mulcahy at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

MAPFRE may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§ 422.660-684 and 423.650-662. Pursuant to 42 C.F.R. §§ 422.756(b) and 423.756(b), a written request for a hearing must be received by CMS within fifteen (15) calendar days of receipt of this notice, or by October 25, 2012. Please note, however, a request for a hearing will not delay the date specified by CMS when the sanction becomes effective.[1] Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

The request for a hearing must be sent to the CMS Hearing Office at the following address:

Benjamin Cohen
CMS Hearing Officer
Office of Hearings
ATTN: HEARING REQUEST
Centers for Medicare & Medicaid Services
2520 Lord Baltimore Drive
Suite L
Mail Stop: LB-01-22
Baltimore, MD 21244-2670
Phone: 410-786-3169
Email: Benjamin.Cohen@cms.hhs.gov

A courtesy copy of the request should also be sent to the following CMS Official:

[1] If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

Patricia Axt
Director, Division of Compliance Enforcement
Program Compliance and Oversight Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop: C1-22-06
Baltimore, MD 21244
Email: Trish.Axt@cms.hhs.gov
FAX: 410-786-6301

CMS will consider the date the Office of Hearings receives the e-mail or the date it receives the fax or traceable mail document, whichever is earlier, as the date of receipt of the request. The request for a hearing must include the name, fax number and e-mail address of the contact within MAPFRE (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

Pursuant to 42 C.F.R. §§ 422.506(b)(3), 422.510(c) 423.507(b)(3), and 423.509(c) this notice also informs MAPFRE of its opportunity to correct the deficiencies stated in this notice. According to our regulations, MAPFE is solely responsible for the identification, development and implementation of its Corrective Action Plan and for demonstrating to CMS that the underlying deficiencies have been corrected and are not likely to recur.

Please note that we are closely monitoring your organization and MAPFRE may also be subject to other applicable remedies available under law, including the imposition of additional sanctions, penalties, or other enforcement actions as described in 42 C.F.R. Parts 422 and 423, Subparts K and O. CMS believes these issues to be of such a serious nature that if left uncorrected, CMS will consider taking action to immediately terminate your contract.

If you have any questions about this notice, please call or email the enforcement contact provided in your email notification.

Sincerely,

/s/

Gerard J. Mulcahy
Acting Director
Program Compliance and Oversight Group

Enclosures:
Attachment A – Corrective Action Template

cc: Mr. Jonathan Blum, CMS/CM
Mr. Timothy Love, CMS/CM
Mr. Reginald Slaten, CMS/CMHPO/Region II
Ms. Rachel Walker, CMS/CMHPO/Region II
Mr. Mitchell Croll, CMS/CMHPO/Region II
Ms. Militza Flores, CMS/CMHPO/Region II

MAPFRE Life Insurance Company
Corrective Action Plan
For: October 9, 2012 CMS Immediate Intermediate Sanctions
(Suspension of Enrollment and Marketing) for Contract Number H5821
Submission Date: _[insert date]_____
Version Number: _[insert version #]___

Part I

Instructions: For each of the deficiencies cited in the sanction notice, please use the template below to provide ***brief*** summary description of what caused the deficiency, the actions being taken to correct each deficiency and ensure it is not likely to recur, and the projected timeframe for correction.

Part I must not exceed 75 pages.

Part C Organizational Determinations, Appeals and Grievances

MAPFRE's deficiencies:

1. **Failure to process beneficiaries' pre-service requests for medical coverage as organization determinations, in violation of 42 C.F.R. § 422.566(c).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what

specific corrective actions will be taken to reach out to <u>all</u> beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

<u>What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur</u>?

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

<u>What is the Projected Timeframe for Correction of the Deficiency</u>?

[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

2. **Failure to process cases as expedited despite a physician's request to do so, in violation of 42 C.F.R. §§ 422.570(c)(2)(ii) and 422.584(c)(2)(ii).**

<u>What Caused the Deficiency to Occur?</u>

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

<u>What Specific Actions Will Be Taken To Correct the Deficiency?</u>

[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to <u>all</u> beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

<u>What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur</u>?

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

<u>What is the Projected Timeframe for Correction of the Deficiency</u>?

[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and

measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

3. **Insufficient staffing to ensure that enrollees have adequate access to the organization determinations and appeals processes on weekends and holidays, in violation of 42 C.F.R. §§ 422.503(b)(4)(ii) and 422.566(a) and IOM Pub. 100-16, Medicare Managed Care Manual Chapter 3, Section 80.1.**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

4. **Failure to conduct appropriate outreach to the requesting provider or treating physician for missing clinical information, in violation of 42 C.F.R. §§ 422.566 and 422.578 and IOM Pub. 100-16, Medicare Managed Care Manual Chapter 13, Sections 50.1 and 70.5.**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

5. **Failure to consider applicable Medicare coverage criteria when making medical necessity decisions for organization determinations, in violation of 42 C.F.R. § 422.101(b).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged)

noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?

[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

6. **Consistently charging cost-share amounts that are not in accordance with MAPFRE's Explanation of Coverage (EOC) and/or the approved plan bid, in violation of 42 C.F.R. §§ 422.100(d), 422.262(c), 422.270 and 422.504(g)(1)(ii).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?

[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?

[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

7. **Substantial failure to ensure that organization determinations and plan reconsiderations were processed and enrollees notified within the required timeframes, in violation of 42 C.F.R. §§ 422.568(b-f), 422.572(a) and 422.590(a-d).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]
What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

8. **Substantial failure to issue a Notice of Denial of Medical Coverage or Notice of Denial of Payment, as appropriate, for adverse organization determinations, in violation of 42 C.F.R. §§ 422.568(d-e) and 422.572(a) and (e) and IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Sections 40.2.1 and 50.5.**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

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What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]
What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

9. **Failure to forward adverse reconsiderations to the IRE for review, in violation of 42 C.F.R. §§ 422.590 (a)(2), 422.590(b)(2) and 422.590(c).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

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Part D Coverage Determinations, Appeals and Grievances

MAPFRE's Deficiencies:

1. **Failure of MAPFRE's Medical Director to oversee Part D coverage determinations and appeals effectively, in violation of § 42 C.F.R. 423.562(a)(5). The Medical Director did not demonstrate adequate understanding of Part D requirements during the CMS audit, and was not able to articulate what, if any, role she plays in ensuring the clinical accuracy of coverage determinations and redeterminations involving medical necessity.**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

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[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
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2. **Insufficient staffing to ensure that enrollees have adequate access to the coverage determinations and appeals processes on weekends and holidays, in violation of 42 C.F.R. §§ 423.128(d)(1)(iv), 423.504(b)(4)(ii) and 423.566(a), IOM Pub. 100-18, Prescription Drug Benefit Manual Chapter 3, Section 80.1 and Appendix 5 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 40.2, 50.4, 70.7, and 70.8.1.**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

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noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to <u>all</u> beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

<u>What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur</u>?
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<u>What is the Projected Timeframe for Correction of the Deficiency</u>?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

3. **Failure to appropriately categorize and process grievances in accordance with 42 C.F.R. § 423.564 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 20.3.**

<u>What Caused the Deficiency to Occur?</u>

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

<u>What Specific Actions Will Be Taken To Correct the Deficiency?</u>
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[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to <u>all</u> beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

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4. **Failure to ensure that an appropriate health care professional is reviewing adverse coverage determinations in cases of medical necessity, in violation of 42 C.F.R. § 423.566(d).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
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measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

5. **Failure to ensure that an appropriate physician makes decisions for all redetermination requests which are denied for lack of medical necessity, in violation of 42 C.F.R. § 423.590(f)(2) and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 70.6.**

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6. **Failure to consider applicable clinical information from prescribers when rendering a decision, in violation of 42 C.F.R. §§ 423.566(a), 423.578(a) and (b) and 423.586, and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1, 30.2.2, 70.7 and 70.8.1.**

What Caused the Deficiency to Occur?

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What Specific Actions Will Be Taken To Correct the Deficiency?
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7. **Failure to conduct appropriate prescriber outreach before denying coverage requests which contain incomplete clinical information, in violation of 42 C.F.R. §§ 423.566(a) and 423.586 and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1, 30.2.2 and 70.5.**

What Caused the Deficiency to Occur?

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8. **Inappropriately denying drugs for which only a particular use or uses are excluded under Part D without considering the use that was being requested by the prescriber, in violation of 42 C.F.R. §§ 423.120 and 423.578(b) and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Section 20.2.4.**

What Caused the Deficiency to Occur?

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What Specific Actions Will Be Taken To Correct the Deficiency?
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9. **Failure to forward untimely coverage determination and appeal cases to the IRE upon expiration of the adjudication timeframe, in violation of 42 C.F.R. §§ 423.568(h), 423.572(d), 423.590(c) and 423.590(e), and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 40.2, 50.6, 70.7.1, 70.8.2, and 70.10.**

<u>What Caused the Deficiency to Occur?</u>

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<u>What Specific Actions Will Be Taken To Correct the Deficiency?</u>
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10. Failure to process coverage determinations and appeals within the required timeframes, in violation of 42 C.F.R. §§ 423.568(b), 423.572(a), 423.590(a) and 423.590(d), and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18 of the Medicare Prescription Drug Manual, Sections 30, 40.2 50.4, 70.7, 70.8.1, 130.1 and 130.2.

What Caused the Deficiency to Occur?

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What Specific Actions Will Be Taken To Correct the Deficiency?
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11. Failure to send appropriate denial letters to beneficiaries stating the specific reason(s) for the denial, in violation of 42 C.F.R. §§ 423.568(f-g), 423.572(c)(2) and 423.590(g), and IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 40.3.4, 50.5, 70.9.1 and 70.9.2.

What Caused the Deficiency to Occur?

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12. Failure to effectuate decisions in its system appropriately in violation of 42 C.F.R. § 423.578(c) and IOM Pub. 100-18 Prescription Drug Benefit Manual

Chapter 18, Section 30.2, which requires that approved exceptions be extended through the end of the plan year. Examples: In several cases, the approval for an exception request did not extend through the plan year. In some cases, approvals were entered into the system before the clinician reviewed and approved the determination. Additionally, the plan was approving prescriptions at a specific strength level instead of approving the drug under all strength levels.

What Caused the Deficiency to Occur?

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What Specific Actions Will Be Taken To Correct the Deficiency?
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[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
[For this heading, enter a brief summarized statement of what specific mechanisms will be instituted to ensure the deficiency is not likely to recur.]

What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

Compliance Program

MAPFRE's Deficiencies:

1. **Failure to provide compliance training upon hire and annually thereafter to its Board members, senior management, and employees, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
[For this heading, enter a brief summarized statement of the corrective action(s) to be taken to correct the deficiency.]

[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to all beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
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What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

2. **Failure to provide fraud, waste and abuse training upon hire and annually thereafter to its Board members, senior management, and employees, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
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What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

3. **Failure to establish and implement an effective system for identification of compliance risks, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
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What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
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What is the Projected Timeframe for Correction of the Deficiency?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

4. **Failure to establish and implement a system for monitoring of compliance program effectiveness, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).**

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
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[Also, for any deficiencies where there was a beneficiary impact (e.g., lack of proper access to prescription drugs or health care services and/or improper cost sharing or premiums charged) noted by CMS in the Sanction Notice or where sponsor's correction action analyses efforts reveal beneficiaries were adversely affected by a particular deficiency, sponsor is expected to

identify the number of beneficiaries affected by the non-compliance (modified numbers need to be provided if determined by the sponsor during the corrective action process to be greater than the numbers noted in the Sanction Notice), to provide CMS with information concerning what specific corrective actions will be taken to reach out to <u>all</u> beneficiaries that were affected by the non-compliance, and whether or not all affected beneficiaries have received the drug or health care service that should have been provided and/or have been reimbursed for any out of pocket costs or premiums improperly incurred.]

<u>What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur</u>?
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<u>What is the Projected Timeframe for Correction of the Deficiency</u>?
[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

5. **Failure to establish and implement a system for auditing compliance program effectiveness, in violation of42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).**

<u>What Caused the Deficiency to Occur?</u>

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

<u>What Specific Actions Will Be Taken To Correct the Deficiency?</u>
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What Specific Actions Will Be Taken To Ensure It Is Not Likely to Recur?
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[For this heading, enter the project timeframe for correcting the deficiency. Timeframes should include (at a minimum) milestones with actions planned; check-in points for demonstrable and measurable progress determinations; projected target dates (month and year); identified material weaknesses; and accountable parties.]

6. Failure to establish and implement procedures and a system to investigate potential FWA problems as identified in the course of self-evaluations and audits, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 423.504(b)(4)(vi)(G).

What Caused the Deficiency to Occur?

[For this heading, enter a brief summarized description of the "root cause" of the deficiency that resulted from sponsor's analysis of the non-compliance in order to properly effectuate correction.]

What Specific Actions Will Be Taken To Correct the Deficiency?
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7. **Failure to establish and implement a system to ensure appropriate corrective actions are taken when instances of noncompliance or FWA are identified, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(G) and 423.504(b)(4)(vi)(G).**

What Caused the Deficiency to Occur?

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8. **Failure to establish and implement effective FWA training for its first tier, downstream, and related entities (FDRs) upon contracting and annually thereafter, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C).**

What Caused the Deficiency to Occur?

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What Specific Actions Will Be Taken To Correct the Deficiency?
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9. Failure to ensure that compliance and FWA reporting mechanisms are accessible and well-publicized to FDRs, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(D) and 423.504(b)(4)(vi)(D).

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10. Failure to establish and implement a system for routine monitoring of their FDRs to ensure compliance with CMS regulations, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).

What Caused the Deficiency to Occur?

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11. Failure to establish and implement a system for auditing of their FDRs to ensure compliance with CMS regulations, in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).

What Caused the Deficiency to Occur?

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PART II

Instructions: Using the projected timeframes provided above, create a timeline reflecting all planned corrective action. This timeline will be a detailed outline of a plan of action to correct all noted deficiencies. It should include (at a minimum) milestones with actions planned, projected completion dates, and accountable parties.

Deficiency # (from Part I)	Milestone/Activity Description	Accountable Parties	Projected Completion Date

Corrective Action Documentation Submitted By:

[Name]
[Title]
[Company]
[Address]
[Phone Number]
[Email Address]

(Signature) **(Date)**