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

MEDICARE PARTS C AND D OVERSIGHT AND ENFORCEMENT GROUP

January 24, 2014

VIA EMAIL (mschrader@caloptima.org)

Mr. Michael Schrader
Chief Executive Officer
Orange County Health Authority
505 City Parkway West
Orange, CA 92868
Phone: (714) 246-8570

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug Plan Contract Number: Orange County Health Authority (CalOptima) (H5433)

Dear Mr. Schrader:

Pursuant to 42 C.F.R. §§ 422.756 and 423.756, the Centers for Medicare & Medicaid Services (CMS) hereby informs Orange County Health Authority (CalOptima) of its determination to immediately impose intermediate sanctions on the following Medicare Advantage-Prescription Drug Plan (MA-PD) Contract: H5433.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into CalOptima plans (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 January 24, 2014, 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 CalOptima'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 CalOptima with detailed instructions regarding the marketing and enrollment suspensions in a separate communication.

CMS has determined that CalOptima 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 CalOptima's Orange, California offices from November 4, 2013, through November 15, 2013. During the audit, CMS conducted reviews of numerous operational areas to determine if CalOptima is following CMS rules, regulations, and guidelines. CMS auditors concluded that CalOptima substantially failed to comply with CMS requirements regarding Part C and Part D appeals and grievances, organization/coverage determinations, Part D formulary and benefit administration, special needs plan model of care, and the adoption and implementation of an effective compliance program in violation of 42 C.F.R. Part 422, Subparts B, C, F, K, and M and 42 C.F.R. 423, Subparts C, K and M. CMS found that CalOptima's failures in these areas were widespread and systemic. Violations resulted 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 the applicable 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 423.568, 423.570(b), 423.578(a). 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 process 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).

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

CMS identified multiple, serious violations on almost all files reviewed in the course of the audit. There were significant violations of Part C and Part D requirements in CalOptima's grievances, organization determinations, coverage determinations and appeals operations that pose a serious threat to the health and safety of enrollees. The audit results indicate that CalOptima's performance issues are widespread and systemic in nature. CalOptima's violations include:

Part C

- Failure to timely and correctly make organization determinations and notify enrollees of decision outcomes for services on a standard or expedited basis. This is in violation of 42 C.F.R. §§ 422.568(b), 422.572(a); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Sections 40.1, 40.2, 50.1, and 50.4.
- Failure to process provider payment requests within the required timeframes. This is in violation of 42 C.F.R. §§ 422.520(a), 422.568(c); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 40.1.
- Failure to pay for emergency medical services. This is in violation of 42 C.F.R. § 422.113(b-c); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 4, Section 20.2. More specifically, sponsor regularly required a prior authorization for all hospital stays admitted through the emergency room before payment would be issued.
- Failure to include the specific reason(s) for an adverse decision in payment denial letters to non-contracted providers. This is in violation of 42 C.F.R. §§ 422.520(a), 422.568(e); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 40.2.3.
- Failure to notify non-contracted providers of their applicable appeal rights when denying requests for payment. This is in violation of 42 C.F.R. § 422.568(e); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 40.2.3.
- Failure to properly distinguish between an organization determination, an appeal, and a grievance. This is in violation of 42 C.F.R. §§ 422.564(b), 422.566; IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Sections 10.2, and 20.2.
- Failure to include the specific reason(s) for an adverse decision in denial letters to beneficiaries. This is in violation of 42 C.F.R. § 422.568(d) and (e); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 40.2.2.
- Failure to appropriately consider clinical information when rendering a decision. This is in violation of 42 C.F.R. §§ 422.566(a), 422.586; IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Sections 40.1, 50.2, and 70.5.

- Failure to appropriately process grievances within the required timeframes. This is in violation of 42 C.F.R § 422.564(e); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 20.3.
- Routinely forwarded timely appeal requests to the IRE for dismissal instead of processing the reconsideration within CMS required timeframes. This is in violation of 42 C.F.R. § 422.582(b); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 13, Section 60.1.1.

Part D

- Failure to forward untimely coverage determination and appeal cases to the IRE upon expiration of the adjudication timeframe. This is in violation of 42 C.F.R. §§ 423.568(h), 423.572(d), 423.590(c), 423.590(e); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 40.4, 50.6, 70.30, and 70.40.
- Failure to process reimbursement requests as coverage determinations and issue payments to beneficiaries within the required timeframes. This is in violation of 42 C.F.R. § 423.568(c); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 40.2 and 130.
- Failure to explain the condition of approval in a readable and understandable form in notice letters for favorable decisions. This is in violation of 42 C.F.R. §§ 423.568(e), 423.572(c)(1), 423.590(h); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Section 40.3.5.
- Failure to timely and correctly effectuate plan coverage determinations on a standard or expedited basis. This is in violation of 42 C.F.R. §§ 423.568, 423.572(a); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 50.4 and 130.1.
- Failure to notify beneficiaries (or prescribers) of their applicable appeal rights for coverage determinations and redeterminations when denying them coverage. This is in violation of 42 C.F.R. §§ 423.572(c), 423.568(g), 423.590(g).
- Failure to include the specific reason(s) for an adverse decision in denial letters to beneficiaries (and prescribers). This is in violation of 42 C.F.R. §§ 423.568(g), 423.572(c)(2), 423.590(g).
- Failure to effectuate decisions in its system appropriately in violation of 42 C.F.R. § 423.578(c); 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.
- Failure to notify the beneficiary or his or her prescriber of its decision within 72 hours of receipt of the expedited redetermination request. This is in violation of 42 C.F.R. § 423.590(d); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 70.9.3 and 70.9.4.
- Failure to appropriately consider clinical information from prescribers when rendering a decision. This is in violation of 42 C.F.R. §§ 423.566(a), 423.578(a), (b), 423.586; Internet Only Manual 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. This is in violation of 42 C.F.R. §§ 423.566(a),

423.586; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Section 30.

- Failure to ensure that the initiation of the coverage determination, redetermination, or grievance was by an authorized representative of the beneficiary. This is in violation of 42 C.F.R. §§ 423.566(a); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1.3, 30.2.2.3, 70.5, and 70.7.
- Failure to process verbal requests as coverage determinations. This is in violation of 42 C.F.R. §§ 423.568(a), 423.570(b), 423.570(c)(1-2); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 40.1 and 50.1.
- Failure to properly distinguish between a coverage determination, an appeal, and a customer service inquiry. This is in violation of 42 C.F.R. § 423.564(b); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Sections 20.2, 20.2.4.1, 20.2.4.2, and 30.4.
- Failure to establish an adequate process for tracking and maintaining records about the receipt and disposition of grievances. This is in violation of 42 C.F.R. § 423.564(g); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18, Section 20.3.
- Failure to appropriately process grievances. This is in violation of 42 C.F.R. § 423.564(a); Medicare Prescription Drug Benefit Manual Chapter 18, Section 20.3.

Part D Formulary & Benefit Administration Requirements

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan sponsors and to Medicare Advantage sponsors that offer prescription drug benefits. Sponsors of these plans (Part D Sponsors) are required to enter into an agreement with CMS by which the sponsor agrees to comply with a number of requirements based upon statute, regulations, and program instructions.

Formulary

42 C.F.R. §§ 423.120(b)(2)(iv) and 423.120(b)(4)-(6); Internet Only Manual (IOM) Pub.100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.3.

Each Part D sponsor maintains a drug formulary or list of prescription medications covered by the sponsor. A number of Medicare requirements govern how Part D sponsors create and manage their formularies. Each Part D sponsor is required to submit its formulary for review and approval by CMS on an annual basis. A Part D sponsor can change its formulary mid-year, but in order to do so must first obtain prior CMS approval, and then notify its enrollees of any changes, in addition to changes in cost-sharing amounts for formulary drugs. The CMS formulary review and approval process includes a review of the Part D sponsor's proposed drug utilization management processes to adjudicate Medicare prescription drug claims (Part D claims).

Utilization Management Techniques

42 C.F.R. § 423.272(b)(2); IOM Pub.100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2; Health Plan Management System (HPMS) Memo, CMS Part D Utilization Management Policies and Requirements Memo, October 22, 2010.

Prior authorization is a utilization management technique used by Part D sponsors (as well as commercial and other health insurers) that requires enrollees to obtain approval from the sponsor for coverage of certain prescriptions prior to being dispensed the medication. Part D enrollees can find out if prior authorization is required for a prescription by asking their physician or checking their plan's formulary (which is available online). Prior authorization guidelines are determined on a drug-by-drug basis and may be based on Food and Drug Administration (FDA) and manufacturer guidelines, medical literature, safety, appropriate use, and benefit design.

Quantity limits are another utilization management technique used by Part D sponsors. A sponsor may place a quantity limit on a drug for a number of reasons. A quantity limit may be placed on a medication as a safety edit based on FDA maximum daily dose limits. Quantity limits may also be placed on a drug for dosage optimization, which helps to contain costs.

In addition, Part D sponsors (as well as commercial and other health insurers) use step therapy to ensure that when enrollees begin drug therapy for a medical condition, the first drug chosen is cost-effective and safe and other more costly or risky drugs are only prescribed if they prove to be clinically necessary. The goal of step therapy is to control costs and minimize clinical risks.

Protected Class Drugs

§ 1860D-4(b)(3)(G) of the Social Security Act; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Section 30.2.5.

Part D sponsors must include all protected class drugs on their formularies, with very limited exceptions. The six protected classes are:

- Anti-depressants (e.g., Fluoxetine, Venlafaxine, Sertraline);
- Antipsychotics (e.g., Risperdal, Zyprexa, Seroquel);
- Anticonvulsants (e.g., Divalproex, Lyrica, Carbamazepine);
- Antiretrovirals;
- Antineoplastics; and
- Immunosuppressants for the treatment of transplant rejection.

Violations Related to Formulary & Benefit Administration

CMS identified serious violations of Part D requirements in CalOptima's formulary and benefit administration operations that pose a serious threat to the health and safety of enrollees. CalOptima's violations include:

- Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits. This is in violation of 42 C.F.R. § 423.120(b)(2); IOM Pub. 100-18

Medicare Prescription Drug Benefit Manual Chapter 6, Sections 30.2 and 30.2.2.1; Chapter 7, Section 60.6.

- Failure to properly administer its CMS-approved formulary by applying unapproved utilization management practices. This is in violation of 42 C.F.R. § 423.120(b)(2); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Sections 30.2, 30.2.5, and 30.3.3.1.
- Failure to properly administer its CMS-approved formulary by rejecting formulary medications as non-formulary. This is in violation of 42 C.F.R. § 423.120(b)(2), IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 6, Sections 30.2, 30.2.5, and 30.3.3.1.
- Failure to provide coverage for protected class drugs. This is in violation of § 1860D-4(b)(3)(G) of the Social Security Act.

Part C Special Needs Plans Model of Care Requirements

All Medicare Advantage Organizations that offer a Special Needs Plan (SNP) are required to create and implement a model of care (MOC) that addresses the needs of the targeted group of beneficiaries enrolled in that SNP. 42 C.F.R. § 422.101(f). The MOC serves as the framework for care, and must be tailored to meet the needs of the beneficiaries it serves. The MOC provides an infrastructure for promoting quality care management and coordination, and is considered a vital quality improvement tool. Among other requirements, Medicare Advantage Organizations that offer SNPs must understand the populations they serve, assess their enrollees at least annually, coordinate care effectively, have the appropriate provider networks in place, and have a quality improvement performance plan. CalOptima offers a Dual-Eligible SNP (D-SNP) which enrolls beneficiaries entitled to Medicare as well as Medical Assistance from a state plan.

Violations Related to Special Needs Plans Model of Care Requirements

The audit revealed violations in CalOptima's management of its D-SNP. CalOptima's violations include:

- Failure to verify the beneficiary's dual eligibility prior to enrollment in the D-SNP. This is in violation of 42 C.F.R. § 422.52; Medicare Managed Care Manual Chapter 2,, Section 20.11, Paragraphs 1, 2, and 3 (*available at* http://cms.hhs.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/index.html); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 16b, Section 50.2.
- Failure to maintain records that the sponsor sent a seamless conversion notice to D-SNP beneficiaries. This is in violation of 42 C F.R. § 422.118, IOM Pub. 100-16 Medicare Managed Care Manual Chapter 2, Sections 40.1.5, B. 3 and 4; Chapter 16b, Section 50.8.
- Failure to administer the initial health risk assessment to beneficiaries within 90 days of their enrollment. This is in violation of 42 C.F.R. §§ 422.101(f)(1)(i), 422.152(g)(2)(iv); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 16b, Section 90.8, Paragraphs 1-Bullet 2, 2, and 3.

- Failure to administer the comprehensive annual reassessment within 12 months of the last risk assessment. This is in violation of 42 C.F.R. §§ 422.101(f)(1)(i), 422.152(g)(2)(iv); IOM Pub. 100-16 Medicare Managed Care Manual Chapter 16b, Section 90.8.
- Failure to provide documented evidence and maintain records of an individualized care plan (ICP) for beneficiaries. This is in violation of 42 C.F.R. §§ 422.101(f)(1)(ii), 422.118; IOM Pub. 100-16 Medicare Managed Care Manual Chapter 16b, Section 90.9, Paragraph 1, Bullet 4.

Violations Related to Compliance Program

In addition to the extensive violations of Part C and D requirements which create a serious threat to enrollee health and safety, CMS's audit determined that CalOptima 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.

CalOptima's compliance program violations discovered during the audit include:

- Failure to distribute standards of conduct and policies and procedures to employees and first tier, downstream, and related entities, within the required timeframes. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(A) and 423.504(b)(4)(vi)(A).
- Failure to demonstrate that compliance training is provided upon hire and annually thereafter to Board members, senior management, and employees. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(C) and 423.504(b)(4)(vi)(C).
- Failure to demonstrate that fraud, waste, and abuse training is provided upon hire and annually thereafter to Board members, senior management, and employees. This is 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. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).
- Failure to demonstrate the establishment and implementation of a system for monitoring and auditing compliance program effectiveness. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F).
- Failures to establish and implement a system to ensure appropriate corrective actions are taken when instances of noncompliance or potential FWA are identified. This is 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 fraud, waste, and abuse training for its first tier, downstream, and related entities (FDRs) upon contracting and annually thereafter. This is 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 a system for routine monitoring of FDRs to ensure compliance with CMS regulations. This is 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 of their FDRs to ensure compliance with CMS regulations. This is 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 CalOptima's deficiencies provide a sufficient basis for the immediate imposition of intermediate sanctions (42 C.F.R. §§ 422.752(b) and 423.752(b)).

- CalOptima 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));
- CalOptima 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) 423.509(a)(2)); and
- CalOptima 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)).

CalOptima's Deficiencies Create a Serious Threat to Enrollee Health and Safety

CalOptima has experienced widespread and systemic failures impacting CalOptima's enrollees' ability to access health care services and prescription medications. Enrollee access to services and prescribed medications is the most fundamental aspect of the Part C and Part D programs because it most directly affects clinical care. CalOptima is denying enrollees access to drugs and services at the point of sale and within their appeals and coverage/organization determinations process. The severity of CalOptima's conduct is magnified by the fact that more than 99% of its enrollees are beneficiaries who receive the low income subsidy (LIS) and who are likely unable to afford to buy medication that is not covered by their insurance.

The nature of CalOptima's noncompliance provides sufficient basis for CMS to find the presence of a serious threat to enrollees' health and safety, supporting the immediate suspension of CalOptima's enrollment and marketing activities. Consequently, these sanctions are effective on January 24, 2014 at 11:59 p.m. EST, pursuant to the authority provided by 42 C.F.R. § 422.756(c)(2) and 423.756(c)(2).

Effect on Other Contracts with CMS

CalOptima was selected to participate in the California Financial Alignment Demonstration and executed a three-way contract with the State of California and CMS (H8016). As stated in the guidance issued by CMS on March 29, 2012[1], CMS will not consider an organization eligible to offer a demonstration plan if it is currently under a Medicare enrollment or marketing sanction,

[1] Memorandum titled Additional Guidance on the Medicare Plan Selection Process for Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans in 2013. Issued March 29, 2012.

and CMS will consider an organization's previous performance in the Medicare program for purposes of permitting new enrollees to be passively enrolled into an approved demonstration plan. On January 9, 2013[2], CMS guidance explained that an organization that is sanctioned after the execution of a contract will be unable to enroll any members until the sanction is lifted. CMS has determined that as a result of these sanctions, CalOptima will not be allowed to enroll any members under contract H8016, either through passive or opt-in enrollment, until the sanctions are lifted. These sanctions will not prevent CalOptima from enrolling new members in their Program of All-Inclusive Care for the Elderly (PACE) (H7501) contract with CMS.

Opportunity to Correct

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 sanctions determination have been corrected and are not likely to recur. To test whether these deficiencies have been corrected, CMS will conduct another program audit in all operational areas cited in this notice at a date no sooner than July 24, 2014, or 180 calendar days from the date of this notice. However, CalOptima may attest to the correction of these deficiencies before the expiration of this time period, at which time CMS will begin its audit procedures shortly after that time. Upon completion of the audit, CMS will make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely recur, or whether other applicable remedies available under law, including the imposition of additional sanctions, penalties, contract termination, or other enforcement actions as described in 42 C.F.R. Part 423, Subparts K and O, are warranted.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. §§ 422.756(a)(2) and 423.756(a)(2), CalOptima has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by February 4, 2014. Please note that CMS considers receipt as the day after the notice is sent by fax, email, or overnight mail, or in this case, January 25, 2014. If you choose to submit a rebuttal, please send it to the attention of Michael DiBella 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

CalOptima 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 February 10, 2014. Please note, however, a request for a hearing will not delay the date specified by CMS when the sanctions become effective.[3] Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

[2] Memorandum titled 2014 Capitated Financial Alignment Demonstration Timeline. Issued January 9, 2013.
[3] If the 15th day falls on a weekend or federal holiday, you have until the next regular business day to submit your request.

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:

Michael DiBella
Director, Division of Compliance Enforcement
Medicare Parts C and D Oversight and Enforcement Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop: C1-22-06
Baltimore, MD 21244
Email: michael.dibella@cms.hhs.gov
FAX: 410-786-4480

CMS will consider the date the Office of Hearings receives the email 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 CalOptima (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 CalOptima of its opportunity to correct the deficiencies stated in this notice. According to CMS regulations, CalOptima 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 CalOptima 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 will consider taking action to immediately terminate your contract if additional issues that pose a serious threat to the health and safety of Medicare beneficiaries are identified or left uncorrected.

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
Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Ms. Elizabeth Richter, CMS/CM
Ms. Cynthia Tudor, CMS/CM
Ms. Melanie Bella, CMS/MMCO
Ms. Ann Duarte, CMS/CMHPO/Region IX
Ms. Deanna Gee, CMS/CMHPO/Region IX
Ms. Susan Castleberry, CMS/CMHPO/Region IX