

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 21, 2016

Mr. Herb Fritch
President
Cigna-HealthSpring
530 Great Circle Road, MR 803
Nashville, TN 37228

Re: Notice of Imposition of Immediate Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H0150, H0354, H0439, H1415, H2108, H2165, H2676, H3945, H3949, H4407, H4454, H4513, H4528, H5410, H6751, H6972, H7020, H7787, H8423, H9460, H9725, and S5617

Dear Mr. Fritch,

Pursuant to 42 C.F.R. §§ 422.756 and 423.756, the Centers for Medicare & Medicaid Services (CMS) is providing notice to HealthSpring of Alabama, Inc., Cigna Healthcare of Arizona, Inc., HealthSpring of Tennessee, Inc., HealthSpring Life & Health Insurance Company, Inc., Cigna Health and Life Insurance Company, Cigna Healthcare of Georgia, Inc., Bravo Health Mid-Atlantic, Inc., Bravo Health Pennsylvania, Inc., Cigna Healthcare of South Carolina, Inc., Cigna Healthcare of North Carolina, Inc., and HealthSpring of Florida, wholly owned subsidiaries of Cigna Corporation (Cigna), that CMS has made a determination to impose intermediate sanctions on the following Medicare Advantage-Prescription Drug and Prescription Drug Plan Contract Numbers: H0150, H0354, H0439, H1415, H2108, H2165, H2676, H3945, H3949, H4407, H4454, H4513, H4528, H5410, H6751, H6972, H7020, H7787, H8423, H9460, H9725, and S5617.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into Cigna's contracts (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 21, 2016, 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 Cigna'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 Cigna with detailed instructions regarding the marketing and

enrollment suspensions in a separate communication.

A Medicare Advantage organization and Prescription Drug Plan 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. CMS has determined that Cigna substantially failed to provide its enrollees with services and benefits in accordance with CMS requirements.

Summary of Noncompliance

CMS conducted an audit of Cigna's Medicare operations from October 5, 2015 through October 20, 2015. During the audit, CMS conducted reviews of numerous operational areas to determine if Cigna is following CMS rules, regulations, and guidelines. CMS auditors concluded that Cigna substantially failed to comply with CMS requirements regarding Part C and Part D organization/coverage determinations, appeals and grievances; Part D formulary and benefit administration; access to facilities and records; and compliance program effectiveness in violation of 42 C.F.R. Part 422, Subparts K and M and 42 C.F.R. 423, Subparts C, K, and M. CMS found that Cigna's failures in these areas were widespread and systemic. Violations resulted in enrollees experiencing delays or denials in receiving medical services and prescription drugs, and increased out of pocket costs for medical services and prescription drugs.

Cigna has had a longstanding history of non-compliance with CMS requirements. Cigna has received numerous notices of non-compliance, warning letters, and corrective action plans from CMS over the past several years. A number of these notices were for the same violations discovered during the audit, demonstrating that Cigna has not corrected issues of non-compliance.

Cigna's acquisition of HealthSpring, Inc. in 2012, which expanded its presence in the Medicare segment and added more than 1 million beneficiaries to Cigna's existing operations, contributed to creating an organizational structure that is decentralized and fragmented. On December 9, 2015, members of Cigna's senior leadership met with CMS to discuss the serious nature of the deficiencies discovered during the audit. At that time, Cigna discussed with CMS that an integration of operations among its various legal entities is necessary to run an effective organization. This breakdown in its operations has made it difficult for Cigna to adequately monitor and oversee whether it is in compliance with the Medicare Parts C and D requirements and has resulted in substantial failures that require considerable correction in order for Cigna to return to a state of compliance with CMS.

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

(42 C.F.R. Part 422, Subpart M; 42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18; IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13)

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. 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). 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. 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 benefit.

If the organization or coverage determination is adverse (not in favor of the beneficiary), the beneficiary has the right to file an appeal. 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. The second level of appeal is made to an independent review entity (IRE) contracted by CMS.

There are different decision making timeframes for the review of organization determinations, coverage determinations, and appeals. 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.

Violations Related to Part C and Part D Organization/Coverage Determinations, Appeals and Grievances

CMS identified serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in Cigna's enrollees experiencing inappropriate delays and denials of medical services and medications. In addition, enrollees received inaccurate and/or incomplete information from Cigna, and experienced inappropriate and untimely resolution of their coverage requests and grievances.

Cigna's violations include:

1. Failure to conduct required outreach to providers or to beneficiaries to obtain information necessary to make appropriate clinical decisions.
 - a. When enrollees requested approval for medical services covered by Part C, Cigna, in numerous cases made determinations based on only the information provided in the initial request for medical services, rather than contacting providers to gather additional information that may have aided in approving the request. As a result, enrollees were inappropriately denied medical

services. This is in violation of 42 C.F.R. § 422.566; and IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 13, Sections 70.7.1 and 70.7.2, and Chapter 4, Section 110.4

- b. In addition, Cigna did not conduct sufficient outreach to providers when receiving requests for drug coverage under Part D. This is in violation of 42 C.F.R. §§ 423.566(a), 423.578, and 423.586; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 18, Sections 10.2, 30.2, 30.2.1.3, 30.2.2.3, 70.5, 70.7, 70.8.
2. Misclassifying Part C reconsiderations as organization determinations. When a provider called Cigna to challenge a denial for medical services, Cigna's delegated entity would re-open the pre-service organization determination instead of following the reconsideration (i.e. appeals) process. As a result, enrollees' requests for medical services were not processed at the appropriate level of appeal and, therefore, enrollees were denied a second-level review and the right to an independent review if those services were denied. This is in violation of 42 C.F.R. §§ 422.578 and 422.580; and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Sections 30 and 70.1.
3. Denial letters for Part C organization determinations, Part D coverage determinations and appeals did not include adequate rationales, contained incorrect/incomplete information specific to denials, or were written in a manner not easily understandable by beneficiaries. As a result, enrollees and/or providers received incorrect denial letters and enrollees did not have adequate information concerning the requirements for coverage. This is in violation of 42 C.F.R. §§ 422.568(d), 423.568(g), 423.572(c)(2), and 423.590(g); IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.2; and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 18, Sections 40.3.4, 50.5.1, 70.9.1, and 70.9.3.
4. Failure to pay provider claims within 60 days after receipt of the organization determination request. As a result, 63,733 claims were not paid on time. This is in violation of 42 C.F.R. § 422.520; and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1.
5. Failure to notify beneficiaries and providers (if the providers requested the services) of its determinations within 72 hours of receipt of Part C expedited organization determination and reconsideration requests. As a result, enrollees were not notified of coverage decisions for medical services on time and, therefore, may have experienced delays in receiving medical services. This is in violation of 42 C.F.R. §§ 422.572(a) and 422.590(d)(1); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Sections 50.1, 50.4, and 80.1.
6. Failure to auto-forward or timely auto-forward Part D coverage determinations and/or redeterminations to the Independent Review Entity (IRE) for review and disposition. As a result, enrollees were delayed in receiving access, or denied access, to an independent review, which could result in a lapse in coverage or a delay in access to

- medications. This is in violation of 42 C.F.R. §§ 423.568(h), 423.572(d), 423.578(c), 423.590(c), 423.590(e); and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 18, Sections 40.4, 50.6, 70.7.1., 70.8.2, and 70.10.
7. Failure to provide accurate or complete information in Part C grievance resolution letters. This is in violation of 42 C.F.R. § 422.564(a); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3.
 8. Failure to have procedures for tracking and maintaining records about the receipt and disposition of Part C grievances. This is in violation of §422.564(g); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3.
 9. Dismissed Part C cases prior to the conclusion of the appeal timeframe. As a result, enrollees' requests for coverage may have been inappropriately denied. This is in violation of 42 C.F.R. § 422.582(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Sections 10.4.1 and 60.1.1.
 10. Failure to issue Part C Explanation of Benefits (EOB) notices to enrollees, as required beginning April 1, 2014. This is in violation of Health Plan Management System (HPMS) Memo, Final Part C EOB Model Templates and Implementation of the Part C EOB, March 31, 2014.
 11. Failure to properly oversee its delegated entities responsible for processing Part C organization determinations, appeals and grievances. This is in violation of 42 C.F.R. § 422.562(a)(3); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 11, Sections 110, 110.1, and 110.2, and Chapter 13, Section 10.2

In addition, prior to the audit, CMS requested that Cigna submit data on its Part C organization determinations, Part D coverage determinations and appeals for CMS to evaluate the quality, appropriateness, and timeliness of services and prescription drugs to Cigna's Medicare enrollees. Cigna failed to provide complete and accurate data for 12 of those data requests in violation of 42 C.F.R. §§ 422.504(d), (e), and (f) and 423.505(d), (e), and (f). As a result, auditors were unable to evaluate whether Cigna was processing certain requests for Part D medications, Part C medical services and appeals correctly and within required timeframes.

Cigna has had a history of non-compliance with processing these requests timely. In 2013, Cigna received a notice of non-compliance for failing to process Part D coverage determinations and redeterminations within the required timeframes and failing to auto-forward those untimely decisions to the independent review entity (IRE). Cigna again received a warning letter in 2015 for these same violations. Therefore, there are significant concerns that additional failures in these areas exist beyond those that auditors were able to identify. Consequently, the total number of enrollees that may have been impacted by Cigna's failures cannot be quantified solely based on this most recent audit.

Part D Formulary and Benefit Administration Relevant 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.

Transition of Coverage

(42 C.F.R. § 423.120(b)(3) and IOM Pub.100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.4)

Additionally, a Part D sponsor must provide for an appropriate transition process for enrollees prescribed any Part D drugs that are not on its formulary in certain designated situations. A Part D Sponsor's transition process must address situations in which an individual brings a prescription for a drug that is not on the formulary to a participating pharmacy. This may be particularly true for full-benefit dual eligible (i.e., Medicare and Medicaid) enrollees who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan's benefit relative to their existing medication needs. Part D sponsors must have systems capabilities that allow them to provide a one-time, temporary supply of a non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or quantity limits under a sponsor's utilization management rules). In the long-term care setting, the temporary supply of non-formulary Part D drugs must be for at least 91 days, and may be up to at least 98 days, consistent with the dispensing increment, with refills provided, if needed. The transition process is designed to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

Violations Related to Formulary & Benefit Administration

CMS identified violations of Part D formulary and benefit administration requirements that resulted in Cigna's enrollees experiencing inappropriate denials of coverage at the point of sale. Cigna's violations include:

12. Failure to properly effectuate prior authorization or exception requests. As a result, enrollees experienced inappropriate denials of coverage at the point of sale and were delayed access to prescription drugs, never received the prescription drugs, or incurred increased out-of-pocket costs. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2.2 and Chapter 18, Section 130.
13. Failure to properly administer its CMS-approved formulary by applying unapproved quantity limits. As a result, enrollees experienced inappropriate denials of coverage at the point of sale and experienced delayed access to prescription drugs, never received the prescription drugs, or incurred increased out-of-pocket. This is in violation of 42 C.F.R. § 423.120(b)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Section 30.2, and Chapter 7, Section 60.6.
14. Failure to provide enrollees transition supplies of medications. As a result, enrollees experienced inappropriate denials of coverage for transition-eligible drugs at the point of sale and were delayed access to drugs, never received the drugs, or incurred increased out-of-pocket costs in order to receive the drugs. This is in violation of 42

C.F.R. § 423.120(b)(3); and IOM Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.4.1 and 30.4.5.

Compliance Program Relevant Requirements

(42 C.F.R. §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi); IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 9; IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 21)

Sponsors are required to adopt and implement an effective compliance program, which must include measures that prevent, detect and correct non-compliance with CMS' program requirements. An effective compliance infrastructure is necessary for a sponsor to adequately monitor and oversee its operations as a whole. Serious issues of non-compliance often occur when a sponsor does not dedicate the resources to developing and maintaining an effective compliance program. Some of the most important requirements for an effective compliance program include, but are not limited to: involving the sponsor's senior leaders in issues of non-compliance; developing an effective system for routine monitoring and identifying of compliance risks; promptly responding to compliance issues as they are raised; investigating potential issues of non-compliance and correcting those problems; and monitoring and auditing first tier entities that contract with the sponsor to ensure that they are in compliance with CMS requirements.

Violations Related to Compliance

CMS' audit determined that Cigna is in substantial violation of compliance program requirements. Cigna's violations include:

15. Failure of the compliance officer or his/her designee to provide updates on results of monitoring, auditing, and compliance failures to Cigna's senior leadership. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(B) and 423.504(b)(4)(vi)(B); IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 21, Section 50.2.4; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 9, Section 50.2.4.
16. Failure to establish and implement a formal risk assessment program and an effective system for routine monitoring and auditing of identified compliance risks. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F); IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 21, Section 50.6; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 9, Section 50.6.
17. Failure to have an effective monitoring and auditing work plan that addresses risk associated with Medicare Parts C and D benefits. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F); IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 21, Section 50.6.1; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 9, Section 50.6.1.
18. Failure to maintain thorough documentation of all deficiencies identified and corrective actions taken. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(G)

and 423.504(b)(4)(vi)(G); IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 21, Section 50.7.2; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 9, Section 50.7.2.

19. Failure to develop and implement an effective system for corrective actions required of first tier entities. This is in violation of 42 C.F.R. §§ 422.503(b)(4)(vi)(F) and 423.504(b)(4)(vi)(F); IOM Pub. 100-16, Medicare Managed Care Manual, Chapter 21, Section 50.6.6; and IOM Pub. 100-18, Medicare Prescription Drug Manual, Chapter 9, Section 50.6.6.

Cigna's lack of an effective compliance infrastructure (specifically related to its monitoring and internal controls) is apparent due to the substantial number of failures discovered during the audit, as well as Cigna's inability to provide CMS with complete and accurate data in response to requests for Part C and Part D organization/coverage determinations and appeals.

Basis for Intermediate Sanctions

CMS has determined that Cigna's deficiencies provide a sufficient basis for the imposition of intermediate sanctions (42 C.F.R. §§ 422.752(b) and 423.752(b)). Cigna failed substantially:

- To carry out the terms of its contracts with CMS (42 C.F.R §§ 422.510(a)(1) and 423.509(a)(1));
- 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)(4)(ii) and 423.509(a)(4)(ii));
- To comply with the Part D service access requirements in § 423.120 (42 C.F.R. § 423.509(a)(4)(iv));

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

Cigna has experienced widespread and systemic failures impacting Cigna enrollees' ability to access medical services and prescription medications. In addition to discovering these issues during the CMS program audit, CMS has received numerous complaints from enrollees demonstrating that enrollees are having difficulties accessing medications and services. 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. The lack of a compliance infrastructure, coupled with serious deficiencies of Cigna's administration of the Medicare Parts C and D requirements, resulted in enrollees being denied access to the medical services and drugs that they are entitled to receive.

The nature of Cigna'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 Cigna's enrollment and marketing activities. Consequently, these sanctions are effective on January 21, 2016 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).

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. Cigna 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. Attached to this notice is a Corrective Action Plan template with instructions for Cigna to complete. Cigna should submit its Corrective Action Plan to CMS within seven (7) calendar days from the date of receipt of this notice, or by January 29, 2016. If Cigna needs additional time beyond seven (7) days to submit its Corrective Action Plan, contact your enforcement lead.

Once Cigna has fully implemented its Corrective Action Plan, it must submit to CMS an attestation from Cigna's Chief Executive Officer, or most senior official, stating that Cigna has corrected the deficiencies that are the basis for the sanction and they are not likely to recur.

Hiring of an Independent Auditor

Pursuant to 42 C.F.R. §§ 422.756(c)(3)(i) and 423.756(c)(3)(i), CMS is requiring Cigna to hire an independent auditor to conduct a validation audit of all operational areas cited in this notice and to provide a written report to CMS. Upon completion of the validation 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. CMS will send additional information about the use of an independent auditor in a separate communication.

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. §§ 422.756(a)(2) and 423.756(a)(2), Cigna has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by February 1, 2016. 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 22, 2016. If you choose to submit a rebuttal, please send it to the attention of Vikki Ahern 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

Cigna may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§ 422.641-696 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 8, 2016.¹ Please note, however, a request for a hearing will not delay the date specified by CMS when the sanctions become effective. Your hearing request will be considered officially filed on the date that it is mailed; accordingly, we recommend using an overnight traceable mail carrier.

¹ 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 copy of the hearing request should also be sent to CMS at the following address:

Vikki Ahern
Acting Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
Email: vikki.ahern@cms.hhs.gov

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 Cigna (or an attorney who has a letter of authorization to represent the organization) with whom CMS should communicate regarding the hearing request.

Please note that we are closely monitoring your organization and Cigna 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 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

Enclosure:
Attachment A – Corrective Action Plan Template

cc: Julie Kennedy, CMS/CMHPO/Region VI
Arthur Pagan, CMS/CMHPO/Region VI
Pamela Conroy, CMS/CMHPO/Region VI