

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**

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August 11, 2014

Mr. Martin P. Hauser  
Chief Executive Officer  
SummaCare, Inc.  
10 N. Main Street  
Akron, OH 44308

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug Contract Number: H3660

Dear Mr. Hauser,

Pursuant to 42 C.F.R. § 422.756 and § 423.756, the Centers for Medicare & Medicaid Services (CMS) is providing notice to SummaCare, Inc. (SummaCare) that CMS has made a determination to immediately impose intermediate sanctions on the following Medicare Advantage-Prescription Drug Contract Number: H3660.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into SummaCare's plan (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 August 11, 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 SummaCare'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 SummaCare with detailed instructions regarding the marketing and enrollment suspensions in a separate communication.

CMS has determined that SummaCare failed to provide its enrollees with services and benefits in accordance with CMS requirements. 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.

## **Summary of Noncompliance**

CMS conducted an audit of SummaCare's Medicare operations from June 2, 2014 through June 13, 2014. During the audit, CMS conducted reviews of numerous operational areas to determine if SummaCare is following CMS rules, regulations, and guidelines. CMS auditors concluded that SummaCare substantially failed to comply with CMS requirements regarding Part C and Part D appeals and grievances and organization/coverage determinations in violation of 42 C.F.R. Part 422, Subpart M and 42 C.F.R. 423, Subpart M. CMS found that SummaCare's failures in these areas were widespread and systemic. Violations resulted in enrollees experiencing delays or denials and increased out of pocket costs for medical services and prescription drugs.

### **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 service or benefit. Coverage decisions must be made in accordance with Medicare coverage guidelines, Medicare covered benefits, and each sponsor's CMS-approved coverage policies and prescription drug benefits.

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 organization determinations, 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 multiple, serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in SummaCare's enrollees experiencing inappropriate denials or delays of medications and medical services within enrollees' coverage/organization determinations or appeals. Additionally, enrollees experienced inappropriate out of pocket cost for covered Medicare services and medications. These failures pose a serious threat to the health and safety of enrollees. Many of these issues stem from ineffective monitoring and oversight of SummaCare's Pharmacy Benefit Manager (PBM), which is responsible for SummaCare's coverage determinations. Additionally, SummaCare's lack of internal controls and of consistent procedures resulted in a breakdown in other processes with Part D redeterminations, Part C organization determinations, and Part C reconsiderations and grievances. SummaCare's violations include:

#### **Part D**

1. Sponsor made inappropriate denials when processing coverage determinations or redeterminations. This is in violation of 42 C.F.R. § 423.566(a) and (b); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 30.
2. Sponsor's Medical Director failed to oversee Part D coverage determinations and appeals effectively. The Medical Director did not ensure the clinical accuracy of coverage determinations and redeterminations involving medical necessity. This is in violation of 42 C.F.R. § 423.562(a)(5).
3. Sponsor initiated re-openings of coverage determination and redetermination cases routinely instead of handling the cases as appeals or directing beneficiaries or their authorized representatives to the Independent Review Entity (IRE). This is in violation of 42 C.F.R. § 423.1980(b); and IOM Pub. 100-18 Medicare Prescription Drug Manual, Chapter 18, Section 120.
4. Sponsor did not demonstrate sufficient outreach to prescribers or beneficiaries to obtain additional information necessary to make appropriate clinical decisions. This is in violation of 42 C.F.R. § 423.566(a) and § 423.586; and 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.
5. Sponsor did not process reimbursement requests as coverage determinations. This is in violation of 42 C.F.R. § 423.566(b)(1); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 30.2.

6. Sponsor misclassified coverage determination or redetermination requests as grievances. This is in violation of 42 C.F.R. § 423.564(b); and 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.
7. Sponsor failed 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); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2.2.1 and 30.2 and Chapter 7, Section 60.6.
8. Sponsor failed 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) and § 423.104(a); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.3.3.3 and Chapter 7, Section 20.4.
9. Sponsor did not appropriately auto-forward coverage redeterminations exceeding the CMS required timeframe to the IRE for review and disposition. This is in violation of 42 C.F.R. § 423.590(c) and § 423.590(e); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.7.1 and 70.8.2.
10. Sponsor did not appropriately auto-forward coverage determinations exceeding the CMS required timeframe to the IRE for review and disposition. This is in violation of 42 C.F.R. § 423.568(h) and § 423.572(d); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.4 and 50.6.
11. Sponsor failed to provide written approval letters for standard or expedited coverage determination or redetermination requests. This is in violation of 42 C.F.R. § 423.568(d) and § 423.572(b); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.3.5, 50.5.2, 70.9.2, and 70.9.4.
12. Sponsor failed to provide written denial letters for standard or expedited coverage determination or redetermination requests. This is in violation of 42 C.F.R. § 423.568(f), § 423.590(a)(2), and § 423.590(d)(2); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 10.3.2, 40.3.4, 50.5.1, 70.9.1, and 70.9.3.
13. Sponsor did not notify beneficiaries or their prescribers of its decisions within 7 days of receipt of standard redetermination requests. This is in violation of 42 C.F.R. § 423.590(a); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.7, 70.9.1, and 70.9.2.
14. Sponsor did not notify beneficiaries or their prescribers of its decisions within 72 hours of receipt of expedited redetermination requests. This is in violation of 42 C.F.R. § 423.590(d); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 70.9.3 and 70.9.4.

15. Sponsor did not notify the beneficiaries or their prescribers, as appropriate, of its decision within 72 hours of receipt of standard coverage determinations or, for exceptions requests, the physician's or other prescriber's supporting statements. This is in violation of 42 C.F.R. § 423.568(b); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.2, 40.3.3, 40.3.4, and 40.3.5.
16. Sponsor did not effectuate determinations within 7 days of receipt of standard redetermination requests. This is in violation of 42 C.F.R. § 423.590(a) and § 423.636(a); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 130.2.
17. Sponsor did not effectuate determinations within 72 hours of receipt of expedited redetermination requests. This is in violation of 42 C.F.R. § 423.638(a); and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 130.2.
18. Sponsor did not make payment decisions within 14 days after receipt of coverage determination requests. This is in violation of 42 C.F.R. § 423.568(c); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.2 and 130.1.
19. Sponsor did not take appropriate action, including a full investigation, and/or appropriately addressing all issues raised in grievances. This is in violation of 42 C.F.R. § 423.564(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.
20. Sponsor did not provide appropriate notification for grievance resolutions. This is in violation of 42 C.F.R. § 423.564(e); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.
21. Sponsor denial letters did not include an adequate rationale or contained incorrect information specific to the denial. This is in violation of 42 C.F.R. § 423.564(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.3.4, 50.5.1, 70.9.1, and 70.9.3.
22. Sponsor does not have adequate procedures for tracking and maintaining records about the receipt and disposition of grievances. This is in violation of 42 C.F.R. § 423.564(a); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.
23. Sponsor provided inaccurate or incomplete information in grievance resolution letters. This is in violation of 42 C.F.R. § 423.564(a) and § 423.564(e); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Section 20.3.
24. Sponsor approval letters failed to accurately or fully explain the condition of approval. This is in violation of 42 C.F.R. § 423.568(e), § 423.572(c)(1), and § 423.590(h); and

IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 40.3.5, 50.5.2, 70.9.2, and 70.9.4.

25. Sponsor did not mail written confirmation of determinations within 3 calendar days after first providing oral notification of expedited coverage determinations or redeterminations. This is in violation of 42 C.F.R. § 423.572(b) and § 423.590(d)(2); and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 50.5.1, 50.5.2, 70.9.3, and 70.9.4.

### **Part C**

26. Sponsor did not notify enrollees or their providers, as appropriate, of its decision within 14 calendar days of receipt of pre-service standard organization determination requests. This is in violation of 42 C.F.R. §422.568(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.
27. Sponsor did not effectuate determinations within 14 days of receipt of pre-service standard organization determination requests. This is in violation of 42 C.F.R. §422.568(b); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.
28. Sponsor did not make payment decisions within 60 days after the receipt of organization determination requests. This is in violation of 42 C.F.R. §422.520(a); and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 3.
29. When Sponsor denied requests for payment for non-contracted providers, the remittance advice/notices did not state the specific reason for the denial nor did the notices provide a description of the appeals process. This is in violation of IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 14, Section 40.2.3.
30. Sponsor did not demonstrate sufficient outreach to providers or beneficiaries to obtain additional information necessary to make appropriate clinical decisions. This is in violation of 42 C.F.R. § 422.566(a) and § 422.586; and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Sections 70.7.1 and 70.7.2.
31. Sponsor made incorrect denials when processing reimbursement requests. This is in violation of 42 C.F.R. § 422.566(a); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 30.
32. Sponsor inappropriately classified reconsiderations as organization determinations. This is in violation of 42 C.F.R. § 422.580; and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Sections 70.1, Paragraph 1 and 130.
33. Sponsor failed to correctly determine whether the issues in enrollees' complaints met the definition of a grievance, an appeal, or both, and did not resolve complaints or disputes through the appropriate procedure. This is in violation of 42 C.F.R. § 422.564(b) and §

422.566(b); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Sections 10.2 and 20.2.

34. Sponsor did not take appropriate actions, including a full investigation, and/or appropriately addressing all issues raised in grievances. This is in violation of 42 C.F.R. § 422.564(e)(1); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3.
35. Sponsor failed to notify the enrollees of the resolution of grievances within CMS required timeframes. This is in violation of 42 C.F.R. § 422.564(a); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3.
36. Sponsor's quality of care grievance resolution letters failed to provide enrollees with written notice of their right to file with, and the contact information for, the Quality Improvement Organization. This is in violation of 42 C.F.R. § 422.564(e)(3)(iii); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.2.
37. Denial letters did not include a denial rationale written in a manner that was clearly understandable by beneficiaries. This is in violation of 42 C.F.R. § 422.568(e) and § 422.572 (e); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.2.
38. When Sponsor denied services or payments, in whole or in part, or discontinued/reduced a previously authorized ongoing course of treatment, enrollees were not issued a written notice of determination using the approved notice language. This is in violation of 42 C.F.R. § 422.568(e); and IOM 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.1.

### **Basis for Intermediate Sanctions**

CMS has determined that SummaCare's deficiencies provide a sufficient basis for the immediate imposition of intermediate sanctions (42 C.F.R. § 422.752(b) and § 423.752(b)). SummaCare 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)(5) and § 423.509(a)(5));

### *SummaCare's Deficiencies Create a Serious Threat to Enrollee Health and Safety*

SummaCare has experienced widespread and systemic failures impacting SummaCare's enrollees' ability to access prescription medications and medical 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. SummaCare is denying enrollees access

to drugs and services within their appeals and coverage determinations process. The ineffective oversight of SummaCare's PBM, coupled with serious deficiencies with SummaCare's administration of its Part D coverage determinations, appeals, and grievances, resulted in enrollees being denied access to the drugs and services that they are entitled to receive.

The nature of SummaCare'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 SummaCare's enrollment and marketing activities. Consequently, these sanctions are effective on August 11, 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).

### **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. Attached to this notice is a Corrective Action Plan template with instructions for SummaCare to complete. SummaCare should submit its Corrective Action Plan to CMS within seven (7) calendar days from the date of receipt of this notice, or by August 18, 2014. If SummaCare needs additional time beyond seven (7) days to submit its Corrective Action Plan, contact your enforcement lead.

Once SummaCare has fully implemented its Corrective Action Plan, it must submit to CMS an attestation from SummaCare's Chief Executive Officer, or most senior official, stating that SummaCare has corrected the deficiencies that are the basis for the sanction and they are not likely to recur. Pursuant to 42 C.F.R. § 422.756(c)(3)(i) and § 423.756(c)(3)(i), once SummaCare submits its attestation, CMS will require SummaCare to hire an independent auditor to conduct validation in all operation areas cited in this notice and to provide a validation report to CMS. Upon completion of the validation, CMS will make a determination about whether the deficiencies that are the basis for the sanctions have been corrected and are not likely recur.

Pursuant to 42 C.F.R. § 422.506(b)(3), § 422.510(c), § 423.507(b)(3), and § 423.509(c), SummaCare 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.

### **Opportunity to Respond to Notice**

Pursuant to 42 C.F.R. § 422.756(a)(2) and § 423.756(a)(2), SummaCare has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by August 21, 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, August 12, 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**

SummaCare 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 August 27, 2014.<sup>1</sup> 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.

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:

Michael DiBella  
Director, Division of Compliance Enforcement  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244  
Mail Stop: C1-22-06  
Email: Michael.Dibella@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 SummaCare (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 SummaCare 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.

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

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: Todd Stankewicz, CMS/CMHPO/Region V  
Delores Perteet, CMS/CMHPO/Region V  
Alicia Kimbrew, CMS/CMHPO/Region V