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

October 29, 2014

Ms. Brenda Yee
Chief Executive Officer
Chinese Community Health Plan
445 Grant Avenue
Suite 700
San Francisco, CA 94108

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug Contract Number: H0571

Dear Ms. Yee,

Pursuant to 42 C.F.R. § 422.756 and § 423.756, the Centers for Medicare & Medicaid Services (CMS) is providing notice to Chinese Community Health Plan (CCHP) that CMS has made a determination to immediately impose intermediate sanctions on the following Medicare Advantage-Prescription Drug Contract Number: H0571.

These intermediate sanctions will consist of the suspension of enrollment of Medicare beneficiaries into CCHP'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 October 29, 2014, at 11:59 p.m. EDT, pursuant to 42 C.F.R. § 422.756(c)(2) and § 423.756(c)(2), because it has determined that CCHP'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 CCHP with detailed instructions regarding the marketing and enrollment suspensions in a separate communication.

CMS has determined that CCHP 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 CCHP's Medicare operations from July 28, 2014 through August 8, 2014. During the audit, CMS conducted reviews of numerous operational areas to determine if CCHP is following CMS rules, regulations, and guidelines. CMS auditors concluded that CCHP substantially failed to comply with CMS requirements regarding Part C and Part D appeals and grievances, organization/coverage determinations, and Part D formulary and benefit administration processes in violation of 42 C.F.R. Part 422, Subpart C and M and 42 C.F.R. 423, Subpart C and M. CMS found that CCHP'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 a request for an 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. Failing to properly classify an organization or coverage determination request 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 plan sponsor's CMS-approved coverage policies and prescription drug benefits.

If the organization or coverage determination is adverse (not in favor of the enrollee), the enrollee 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 handled by 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 multiple, serious violations of Part C and Part D organization/coverage determination, appeal, and grievance requirements that resulted in CCHP's enrollees experiencing inappropriate denials or delays of medications and medical services. 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. CCHP's violations include:

Part C

1. Inappropriately denying payment for emergency or urgently-needed medical services. This is in violation of 42 CFR § 422.113 (b) and (c) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 50.2.1 and Medicare Managed Care Manual, Chapter 4, Section 20.2.

2. Failure to obtain concurrence from physicians responsible for beneficiary care before discharging from the inpatient hospital level of care. This is in violation of 42 CFR § 422.620(d) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 150.4.

3. Inappropriately issued a Notice of Denial of Medical Coverage to enrollees during inpatient hospital stays without advising them of their right to file an immediate review with the quality improvement organization (QIO). This is in violation of 42 CFR § 422.620(b), 42 CFR § 422.622 and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 150.1 and Section 150.3.

4. Failure to authorize or pay for medically necessary and/or covered medical services. This is in violation of 42 CFR § 422.101 (a) and (b) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 4, Section 10.2 and Section 10.4.

5. Failure to ensure that reconsiderations were reviewed by an appropriate physician when the initial denial was based on the lack of medical necessity. This is in violation of 42 CFR § 422.590(g)(2) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 70.6.

6. Failure of the Medical Director to ensure clinical accuracy of all organization determinations and appeals. This is in violation of 42 CFR § 422.562(a)(4) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 10.2, Paragraph 3.

7. Failure to notify beneficiaries of its decision within 14 calendar days of receipt of standard organization determination requests. This is in violation of 42 CFR § 422.568(b) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.1, Paragraph 1.

8. Failure to notify beneficiaries of its decision within 72 hours of receipt of expedited organization determination requests. This is in violation of 42 CFR § 422.572(a) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 50.1, Paragraph 1, Bullet 3 and Section 50.4, Paragraph 1, Bullet 1.

9. Failure to notify beneficiaries of its determination within 72 hours of receipt of expedited reconsideration requests. This is in violation of 42 CFR § 422.590(d)(1) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 80.1, Paragraph 3.

10. Failure to issue its reconsidered determination and/or send payment for services within 60 calendar days from the date of receipt. This is in violation of 42 CFR § 422.590(b)(1) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 70.7.3 Paragraph 1 and 2.

11. Failure to prepare and send case files to the IRE within CMS required timeframes upon affirming its adverse decisions on standard payment reconsiderations. This is in violation of 42 CFR § 422.590(b)(2) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 70.7.3 Paragraph 2 and Section 80.4, Paragraph 1, Bullet 3.

12. Failure to notify enrollees that cases were auto-forwarded to the IRE for review and disposition and/or failed to advise the enrollees of their right to submit additional evidence to the IRE. This is in violation of 42 CFR § 422.590(e) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 70.7.2, Paragraph 1 and Section 80.3, Paragraph 2.

13. Failure to provide enrollees written notice of its determination using the approved notice language when denying services or payments, in whole or in part, or discontinuing a previously authorized ongoing course of treatment. This is in violation of 42 CFR § 422.568(d) and (e) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.1, Paragraph 2 and Paragraph 3.

14. Failure to state the specific reason for denial or provide a description of the appeals process in the remittance notice when denying a request for payment from a non-contracted provider. This is in violation of 42 CFR § 422.568(e) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.3.

15. Failure to provide denial notices to enrollees with complete and accurate information specific to the denial and in a readable and understandable form. This is in violation of

42 CFR § 422.568(d) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 40.2.2, Paragraph 1and Paragraph 3.

16. Failure to identify and process beneficiary complaints and disputes as grievances. This is in violation of 42 CFR § 422.564(b) and § 422.566(b) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 10.2 and Section 20.2.

17. Misclassifying organization determination or reconsideration requests as grievances. This is in violation of 42 CFR § 422.564(b) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.2, Paragraph 1.

18. Failure of sponsor's quality of care grievance resolution letters to provide beneficiaries with written notice of their right to file with, and the contact information for, the QIO. This is in violation of 42 CFR § 422.564(e)(3)(iii) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.1 Paragraph 5.

19. Failure to notify the beneficiary of the resolution of the grievance within CMS required timeframes or as expeditiously as the enrollee's case required. This is in violation of 42 CFR § 422.564(e)(1) and IOM Pub. 100-16 Medicare Managed Care Manual, Chapter 13, Section 20.3, Paragraph 2, Bullet 8.

Part D

20. Failure to 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.

21. Failure to notify beneficiaries of its decision within 24 hours of receipt of expedited coverage determination requests or exceptions requests. This is in violation of 42 C.F.R. § 423.572(a) and IOM Pub.100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 50.4.

22. Improperly denying coverage determinations by failing to consider prior use of medication and clinical information. 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, Sections 30.

23. Failure to properly effectuate prior authorization or exception requests. 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 and Chapter 18, Section 130.

24. Misclassifying redetermination requests as coverage determinations. This is in violation of 42 C.F.R. § 423.580 and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 18, Sections 30, 40.3.4 and 70.2.

25. Misclassifying coverage determination or redetermination requests as customer service inquiries. 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.

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.

Violations Related to Formulary & Benefit Administration

CMS identified serious violations of Part D formulary and benefit administration requirements that resulted in CCHP's enrollees experiencing inappropriate denials or delays of medications at the point of sale and receiving incorrect transition notification letters. CCHP's violations include:

26. Failure to properly administer its CMS-approved formulary by applying unapproved prior authorization edits. 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, 30.2.2, and 30.2.2.1.

27. Failure to properly administer its CMS-approved formulary by applying unapproved utilization management practices. This is in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2); 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.

28. 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) and IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2 and 30.2.2.1, and Chapter 7, Section 60.6.

29. Failure to properly administer its CMS-approved formulary by applying unapproved step therapy edits and/or criteria. 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 30.2.2.1.

Basis for Intermediate Sanctions

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

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

CCHP has experienced widespread and systemic failures impacting CCHP's enrollees' ability to access prescription medications and medical services. CCHP has inappropriately denied payment for emergency or urgently-needed medical services and failed to obtain concurrence from

physicians responsible for beneficiary care before discharging from the inpatient hospital level of care. CCHP has denied enrollee's access to services and medications by failing to provide transition supplies of medication to enrollees in accordance with the CMS transition policy and through significant failures within their appeals and grievances process.

Enrollee access to services and prescribed medications is the most fundamental aspect of the Part C and Part D programs. The nature of CCHP'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 CCHP's enrollment and marketing activities. Consequently, these sanctions are effective on October 29, 2014 at 11:59 p.m. EDT, 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 CCHP to complete. CCHP should submit its Corrective Action Plan to CMS within seven (7) calendar days from the date of receipt of this notice, or by November 6, 2014. If CCHP needs additional time beyond seven (7) days to submit its Corrective Action Plan, contact your enforcement lead.

Once CCHP has fully implemented its Corrective Action Plan, it must submit to CMS an attestation from CCHP's Chief Executive Officer, or most senior official, stating that CCHP 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 CCHP submits its attestation, CMS will require CCHP 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), CCHP 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), CCHP has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by November 9, 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, October 30, 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

CCHP 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 November 14, 2014.[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.

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 CCHP (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 CCHP 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

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

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: Ms. Ann Duarte, CMS/CMHPO/Region IX
Mr. Kenneth Gardner, CMS/CMHPO/Region IX
Mr. Max Wong, CMS/CMHPO/Region IX