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

MEDICARE PARTS C & D OVERSIGHT AND ENFORCEMENT GROUP

April 23, 2013

VIA:
EMAIL (pritpal.virdee@smartdrx.com)
AND FACSIMILE (847-906-2441)

Mr. Pritpal Virdee
Chief Executive Officer & President
Smart Insurance Company
1435 Lake Cook Road
Suite C4152
Deerfield, IL 60015
Phone: (636) 346-3680

Re: Notice of Immediate Imposition of Intermediate Sanctions (Suspension of Enrollment and Marketing) for Prescription Drug Plan Contract Number: S0064

Dear Mr. Virdee:

Pursuant to 42 C.F.R. § 423.756, the Centers for Medicare & Medicaid Services (CMS) hereby informs Smart Insurance Company (Smart) of its determination to immediately impose intermediate sanctions on the following Prescription Drug Plan Contract: S0064.

These intermediate sanctions will consist of the suspension of the enrollment of Medicare beneficiaries (42 C.F.R. § 423.750(a)(1)) and the suspension of all marketing activities to Medicare beneficiaries (42 C.F.R. § 423.750(a)(3)). CMS is imposing these intermediate sanctions immediately, effective April 23, 2013, at 11:59 p.m. EST, pursuant to 42 C.F.R. § 423.756(c)(2), because it has determined that Smart's conduct poses a serious threat to the health and safety of Medicare beneficiaries.

A prescription drug plan sponsor's central mission is to provide Medicare enrollees with prescription drug benefits within a framework of Medicare requirements that provide enrollees with a number of protections. CMS has determined that Smart failed to provide its enrollees with services and benefits in accordance with CMS requirements. CMS has further determined that Smart's failures pose a serious risk to its current and prospective members' health and safety and therefore is making the sanction effective immediately.

Smart is a new Part D Sponsor that has experienced significant compliance failures since its first day of operations. Over the last several months, CMS has repeatedly communicated with Smart regarding its poor performance.

In its short tenure as a Part D sponsor, Smart has experienced widespread failures in numerous important operational areas including:

- Smart inappropriately rejected drug claims at the point of sale (i.e., pharmacy counter);
- Smart failed to properly process coverage determinations (i.e., requests for drug coverage or payment and reimbursement);
- Smart denied enrollees the chance to appeal rejected claims and failed to ensure that denied coverage determinations were reviewed by an independent third party; and
- Smart failed to process enrollment and disenrollment requests, or failed to properly process enrollment transactions.

As a result of Smart's noncompliance, its enrollees have experienced delays or denials in receiving prescription drug coverage and increased out-of-pocket costs. Smart's failures violate CMS requirements contained at § 1860D-4(b)(3)(G) of the Social Security Act; 42 C.F.R. Part 423, Subparts B, C, K, and M.

Prescription Drug Program Relevant Requirements

Medicare Part D Prescription Drug Program requirements apply to stand-alone Prescription Drug Plan 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.

To receive Part D benefits, Medicare beneficiaries must elect to enroll in a prescription drug benefit plan offered by a Part D sponsor. Part D sponsors are required to operate systems that adjudicate claims in real time at the point of sale, which is typically a retail pharmacy. 42 C.F.R. § 423.505(b)(17). To operate such a system, Part D sponsors must accurately process enrollment transactions. 42 C.F.R. Part 423, Subpart B. This includes assigning individuals to their elected plans, transmitting enrollment data to CMS and maintaining accurate information on beneficiaries' eligibility for a low-income subsidy (LIS) that would exempt them from liability for premiums and deductibles and afford them access to special low co-payment amounts. 42 C.F.R. Part 423, Subpart B and § 423.800.

Unlike health benefits offered under the Part C or Original Medicare programs, where beneficiary payments and claims are normally processed after the delivery of covered services, outpatient prescription drug claims must be adjudicated in light of the structure (e.g., deductibles and cost sharing amounts) of the beneficiary's plan benefit package in real time at the point of sale and result in an adjudicated paid response before a pharmacy will fill a beneficiary's prescription. 42 C.F.R. §§ 423.104(a) and 423.505(b)(17). Any failure of a sponsor's data systems can immediately cause interruptions in claims processing for its enrollees at the

pharmacy counter. In those instances, the beneficiary will have to leave the pharmacy without the drug unless he or she can pay the entire cost of the drug out of his or her own pocket.

Sponsors must pay particular attention to their enrollment operations each December in preparation for the start of a new plan benefit year the following January. They must make certain that prior to January 1, their enrollment records (upon which the operation of their claims adjudication system will depend) show that the sponsor's continuing enrollees are assigned to the correct benefit plan package for the upcoming year, that new enrollees who elected the sponsor's plan during the annual election period are assigned to the plan they chose, and that the correct LIS status is recorded for each beneficiary. 42 C.F.R. Part 423, Subparts B and § 423.800.

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, a 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, including changes in cost-sharing amounts for formulary drugs, but in order to do so must first obtain prior CMS approval, and then notify its enrollees of any changes. 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 prescribed 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 PDP 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.

Protected class drugs are drugs that are typically critical to the health and safety of the population for whom the drugs are prescribed. The six protected classes are:

- Anti-depressants (e.g., Fluoxetine, Venlafaxine, Sertraline) used for treating depression;
- Antipsychotics (e.g., Risperdal, Zyprexa, Seroquel) used for treating psychiatric disorders;
- Anticonvulsants (e.g., Divalproex, Lyrica, Carbamazepine) used for preventing or reducing seizures;
- Antiretrovirals used for the treatment of HIV and AIDS;
- Antineoplastics used for the treatment of cancers; and
- Immunosuppressants used to prevent the rejection of transplants.

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 drug transition process (i.e., a one-time prescription fill of an existing medication) for new enrollees already established on a non-formulary drug, or who are impacted by a change in a Sponsor's formulary. 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 non-formulary Part D drug (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber 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.

Part D Grievance, Coverage Determination and Appeal Relevant Requirements

42 C.F.R. Part 423, Subpart M; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 18.

A sponsor's grievances, coverage determinations, and appeals operations serve as a "safety net" for improper formulary administration. Medicare enrollees have the right to contact their 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. Generally, sponsors are required to classify and process complaints about coverage for drugs or payment as a request for a coverage determination or appeal. Improper processing of a coverage determination denies an enrollee their due process and appeal rights and may delay an enrollee's access to medically necessary or life-sustaining services or drugs.

The enrollee, the enrollee's appointed representative, or the enrollee's prescribing physician or other prescriber may make a request for a coverage determination. The first level review is the coverage determination, which is conducted by the plan sponsor. If the coverage determination is adverse (not in favor of the enrollee), the enrollee has the right to file an appeal. The first level of appeal is called a redetermination. Redeterminations are processed by the plan sponsor and must be conducted by an individual who was not involved in the 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 coverage determinations and appeals. CMS has a beneficiary protection in place that requires plans to forward coverage determinations and redeterminations to the IRE when the plan has missed the applicable adjudication timeframe.

If the plan sponsor reverses its initial adverse coverage determination or the IRE reverses the plan sponsor's adverse decision, the plan sponsor must correctly authorize or provide the benefit under dispute within the timeframes set forth in regulation. If the plan sponsor does not effectuate the decision timely and correctly, this can result in delays to an enrollee's access to medically necessary or life-sustaining drugs.

Enrollment and Disenrollment

42 C.F.R. Part 423, Subpart B; IOM Pub. 100-18 Medicare Prescription Drug Benefit Manual Chapter 3.

A PDP sponsor must timely process an individual's enrollment request in accordance with CMS enrollment guidelines. When an enrollment request is incomplete, the sponsor must document its efforts to obtain the information required to complete the enrollment request. CMS offers an on-line enrollment center through the www.medicare.gov web site and the 1-800-MEDICARE call center for enrollment into Medicare prescription drug plans. PDP sponsors should retrieve

online enrollment center requests at least daily. The PDP sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

The PDP sponsor must submit a disenrollment transaction to CMS within timeframes CMS specifies; provide the enrollee with a notice of disenrollment as CMS determines and approves; and file and retain disenrollment requests for the period specified in CMS instructions.

Compliance Program

42 C.F.R. § 423.504(b)(4)(vi); IOM Pub. 100-18 Prescription Drug Benefit Manual Chapter 9.

All Medicare Part D Sponsors are required to have an implemented compliance program, effective in detecting, correcting, and preventing Medicare program noncompliance. As part of an effective compliance program, a sponsor must establish and implement systems to monitor and audit its First Tier, Downstream, and Related Entities (FDRs). Sponsors may enter into contracts with FDRs to provide administrative or health care services for enrollees on behalf of the sponsor (e.g., a Pharmacy Benefits Manager (PBM) or a Call Center). However, the sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements.

History of Noncompliance

Smart has experienced extensive failures in its compliance with Medicare Part D requirements, since its first day of operations as a Part D sponsor. As part of CMS's readiness assessment, CMS engaged with Smart to determine its compliance with CMS rules, regulations, and guidance. Smart's noncompliance began during 2013 open enrollment. Since that time, CMS has provided Smart notice and opportunity to correct its operations.

For example, Smart required detailed technical assistance to remedy its failure to operate a toll-free customer service call center at the beginning of the month of January. Due to this failure, Smart enrollees went without access to call center services and information about their benefits.

Smart has also received continued, detailed directions from CMS regarding its prescription drug and transition coverage administration, and point-of-service claims adjudication. Due to improperly applied utilization management techniques, enrollees left the pharmacy without their prescription drugs. Enrollees experienced further delay or denial in accessing their prescription drugs when Smart's coverage determination and redetermination "safety net" operations failed to properly process and determine enrollee claims for coverage.

CMS has repeatedly communicated with Smart about its extensive failures in major Part D operational areas:

- Failure to properly administer its CMS-approved prescription drug benefit;
- Failure to provide timely and appropriate point-of-service claims adjudication;

- Failure to properly administer its CMS-approved formulary by applying unapproved step therapy, prior authorization, and quantity limits;
- Failure to properly adjudicate LIS co-payments;
- Failure to properly process coverage determinations;
- Failure to properly process redeterminations;
- Failure to properly process grievances;
- Failure to operate a toll-free customer service call center;
- Failure to properly process enrollment requests;
- Failure to effectively monitor and oversee internal operations; and
- Failure to effectively monitor and oversee delegated entities.

In March 2013, CMS conducted a validation audit to confirm that Smart had corrected its violations and was operating in accordance with Medicare Part D rules, regulations, and guidance. CMS determined that violations were continuing in a number of areas and that Smart's infrastructure is insufficient to ensure effective Part D operations. Continued violations include:

Prescription Drug and Transition Coverage

- Failure to follow CMS requirements regarding transition supplies of prescription drugs, including failing to provide for the appropriate transition of new enrollees and existing enrollees prescribed Part D drugs that are not on Smart's formulary. This is in violation of 42 C.F.R. § 423.120(b)(3).

- Failure to provide coverage for protected class drugs. This is in violation of § 1860D-4(b)(3)(G) of the Social Security Act.

- Failure to properly administer its CMS-approved prescription drug benefit. This is in violation of 42 C.F.R. § 423.104(a) and § 423.120(b)(2). More specifically, Smart applied an unapproved quantity limit to a prior authorization.

Part D Coverage Determinations and Appeals

- Failure to process coverage determinations and appeals within the required timeframes. This is in violation of 42 C.F.R. §§ 423.568(b), 423.572(a), 423.590(a) and 423.590(d).

- Misclassifying coverage determinations as grievances. This is in violation of 42 C.F.R. § 423.564(b).

- Failure to provide beneficiaries with notice letters for favorable decisions. This is in violation of 42 C.F.R. §§ 423.568(d), 423.572(a), and 423.590(a)(1), (b)(1), and (d).

- 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) and 423.572(c).

- 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 and 423.572.

- Failure to timely and correctly effectuate plan redeterminations on a standard or expedited basis. This is in violation of 42 C.F.R. §§ 423.636 and 423.638.

- 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) and 423.586

- Failure to provide beneficiaries with denial letters. This is in violation of 42 C.F.R. §§ 423.568(f), 423.572(a), and 423.590(a)(2), (b)(2), and (d).

- 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. §§ 423.568(g), 423.572(c)(2), and 423.590(g).

- Failure to notify beneficiaries 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), and 423.568(g), and 423.590(g).

- Failure to forward untimely coverage determinations and redeterminations to the IRE upon expiration of the adjudication timeframe. This is in violation of 42 C.F.R. §§ 423.568(h), 423.572(d), and 423.590(e).

- 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) and (b), 423.586, and Internet Only Manual (IOM) Pub. 100-18 Prescription Drug Benefit Manual Chapter 18, Sections 10.2, 30.2.1, 30.2.2, 70.7, and 70.8.1.

- Failure to classify reimbursement requests as coverage determinations. This is in violation of 42 C.F.R. §§ 423.566(b) and 423.568(c).

- Failure to process reimbursement requests as coverage determinations and issue payments to beneficiaries. This is in violation of 42 C.F.R. §§ 423.568(c).

Enrollment

Failure to comply with Medicare Part D requirements regarding timely processing of enrollment elections, and timely issuance of required enrollment materials to beneficiaries. This is in violation of 42. C.F.R. Part 423, Subpart B.

Compliance Program

- Failure to obtain complete access to relevant information at the First Tier entity level. This is in violation of 42 C.F.R. § 423.504(b)(4)(vi)(F).

- Failure of the monitoring and auditing system to effectively identify significant operational deficiencies. This is in violation of 42 C.F.R. § 423.504(b)(4)(vi)(F).

- Failure to demonstrate that its method for monitoring its FDRs is effective. This is in violation of 42 C.F.R. § 423.504(b)(4)(vi)(F).

- Failure to ensure that the corrective actions taken by First Tier entities were effective. This is in violation of 42 C.F.R. § 423.504(b)(4)(vi)(G).

Legal Basis for Immediate Imposition of Marketing and Enrollment Sanctions

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

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

- Smart 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. § 423.509(a)(2)).

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

Smart has experienced widespread and systemic failures impacting Smart's enrollees' ability to access their prescription medications. Despite extensive communication with CMS since the start of its operations in the Medicare program, Smart has not satisfactorily addressed its serious deficiencies. Beneficiary access to prescribed medications is the most fundamental aspect of the Part D program because it most directly affects clinical care.

The severity of Smart's conduct is magnified by the fact that approximately 85% of its enrollees are LIS beneficiaries who are likely unable to afford to by medication that is not covered by their insurance.

The nature of Smart'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 Smart's

Part D enrollment and marketing activities. Consequently, these sanctions are effective on April 23, 2013, pursuant to the authority provided by 42 C.F.R. § 423.756(c)(2).

Opportunity to Respond to Notice

Pursuant to 42 C.F.R. § 423.756(a)(2), Smart has ten (10) calendar days from the date of receipt of this notice to provide a written rebuttal, or by May 6, 2013. Please note that CMS considers receipt as the day after the notice is sent by fax, e-mail, or overnight mail, or in this case, April 24, 2013. If you choose to submit a rebuttal, please send it to the attention of Gerard J. Mulcahy at the address noted below. Note that the sanctions imposed pursuant to this letter are not stayed pending a rebuttal submission.

Right to Request a Hearing

Smart may also request a hearing before a CMS hearing officer in accordance with the procedures outlined in 42 C.F.R. §§ 423.650-662. Pursuant to 42 C.F.R. § 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 May 9, 2013.[1] Please note a request for a hearing will not delay the date specified by CMS when the sanctions become effective. A hearing request will be considered officially filed on the date that it is mailed; accordingly, CMS recommends 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

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

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

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

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

CMS will provide Smart with detailed instructions regarding the marketing and enrollment suspension in a separate communication. CMS considers these issues to be extremely serious. We are closely monitoring your organization's operations to determine if additional action is warranted. *See* 42 C.F.R. Part 423, Subparts K and O.

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 & D Oversight and Enforcement Group

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