

endorsement, including failing to perform the operational requirements of this program, or the failure to submit an acceptable plan of correction within the time frame specified by CMS; and

Upon determining that at least one basis exists for imposing an intermediate sanction, our regulations at § 403.820(a)(4) provide that we will notify the non-compliant endorsed sponsor of our intent to impose sanctions. The endorsed sponsor will have 15 days to challenge the accuracy of our finding. If the endorsed sponsor does not challenge the finding, the sanctions will go into effect 15 days after the endorsed sponsor received the sanction notice from us. If the endorsed sponsor does challenge the finding, we will notify the sponsor of the effective date in the reconsideration determination notice that we will send to the endorsed sponsor. Once intermediate sanctions are imposed, the endorsed sponsor will be required to demonstrate to us that it has come into compliance with card program requirements before the sanctions are lifted.

3. Civil Monetary Penalties

Section 1860D–31(i)(3) of the Act authorizes the imposition of civil monetary penalties (CMP) against endorsed sponsors that knowingly engage in conduct that violates the requirements of section 1860D–31 of the Act or engage in false or misleading marketing practices. In § 403.820(b) of our regulations, we interpret this to mean that those endorsed sponsors that knowingly engage in conduct that violates the conditions of their endorsement agreement with us or that constitutes false or misleading marketing practices may be subject to CMPs.

We have divided the sanction authority between CMS and the Department of Health and Human Services Office of the Inspector General (OIG). As in Part C, where CMP authority is shared between these two agencies, we have assigned sanction authority to the IG for those violations that concern misleading or defrauding a beneficiary. We have also assigned sanction authority to the IG for misuse of transitional assistance funds. On the other hand, we will have the authority to impose CMPs in those instances where the endorsed sponsor's conduct constitutes non-compliance with an operational requirement not directly related to beneficiary protection. Accordingly, as provided in § 403.820(b)(1) of our regulations, the IG will have the authority to impose CMPs

against an endorsed sponsor whom it determines has knowingly—

(1) Misrepresented or falsified information in information and outreach or comparable material provided to a program enrollee or other persons;

(2) Charged a program enrollee in violation of the terms of the endorsement contract; or

(3) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

As provided in § 403.820(b)(2) of our regulations, we will have the authority to impose CMPs for an endorsed sponsor's—

(1) Substantial failure to maintain an adequate retail pharmacy network;

(2) Substantial failure to comply with our information and outreach guidelines;

(3) Substantial failure to provide us or our designees with requested information related to the endorsed sponsor's drug card operations;

(4) Substantial failure to provide enrollees with levels of discounts or prices consistent with information provided in its marketing materials;

(5) Charging card program enrollees additional fees beyond an enrollment fee, charging transitional assistance-qualified enrollees any enrollment fee, charging a co-payment higher than 10 percent for those above 100 percent of the poverty line and up to 135 percent of the poverty line, or charging a co-payment higher than 5 percent for those at or below 100 percent of the poverty line;

(6) Substantial failure to administer properly the transitional assistance, including the charging of coinsurance, for the endorsed sponsor's eligible enrollees;

(7) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP) and/or an amount proportionate to the changes in the endorsed sponsor's cost structure (including materials changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy); or

(8) Any other failure to substantially comply with the requirements of the endorsement, or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

The CMS and the IG may impose CMPs of up to \$10,000 per violation. We

will impose CMPs and afford endorsed sponsor appeal rights according to the procedures stated in 42 CFR parts 1003 and 1005.

We note that in addition to the sanctions described above, a card sponsor's misuse of the Medicare name or emblem may subject them to the penalties stated at 42 U.S.C. 1320b-10, which prohibits the misuse of the Medicare name or emblem. In general, the statute authorizes the IG to impose penalties on any person who misuses the term, "Medicare," or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to \$5000 per violation or, in the case of a broadcast or telecast violation, \$25,000.

4. Termination by CMS

Pursuant to section 1860D–31(i)(3) of the Act, and as provided in § 403.820(c) we may terminate the contract of any endorsed sponsor upon a determination that the sponsor no longer meets the requirements for participation in the Medicare drug discount card program or that the sponsor has engaged in false or misleading marketing practices (for example, use of non-CMS-approved marketing materials, marketing outside the approved service area, use of beneficiary information to market services not directly related to the endorsed sponsor's Medicare card program). The bases stated above for the imposition of intermediate sanctions also serve as the bases for termination for failure to meet the requirements for participation in the Medicare drug discount card program. Prior to terminating a contract, we will afford the endorsed sponsor an opportunity to develop and execute a CMS-approved corrective action plan.

We will afford an endorsed sponsor the opportunity to appeal our decision to terminate an endorsement contract as well as our decision not to enter into a contract with an entity that applied for endorsement. In each case, we will provide notice to the endorsed sponsor stating the reasons for terminating the contract or failing to endorse the program. These sponsors will have 15 days from the date of the notice to file a request in writing for reconsideration to us. We will then designate a hearing officer who is impartial and has no interest in the matter pending for decision. CMS and the sponsor will have the opportunity to submit evidence and participate in a hearing convened by the hearing officer. The hearing officer will issue a decision as soon as