432, provides that if a PRO finds that a "physician or practitioner has furnished services in violation of section 1156(a) and the organization determines that the physician or practitioner should enter into a corrective action plan under section 1156(b)(1), the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding."

The Secretary may require by regulation that the PRO notify appropriate licensure boards for non-physician practitioners when those practitioners are found in violation. Accordingly, we are revising § 1004.70(c) to include notification by the PRO of appropriate licensure boards when it sends a report to the OIG regarding a physician or other person.

Section 1004.100—Acknowledgement and Review of Report

Comment: While a number of respondents concurred with the content of this section, one commenter stated that if the OIG believes that a particular sanction recommendation is not warranted, procedures should be in place for the OIG to discuss the matter with the PRO before making a final decision. Accordingly, the commenter requested that we add a provision requiring the OIG physician advisor to communicate with one or more of the physicians on the PRO panel.

Response: We disagree with the need for this added requirement. We believe such communication on the part of the OIG physician advisor could raise specific concerns of due process. There would be no clear way for the practitioner or other person to be made aware of the questions raised and the responses made by the PRO through such communication. In addition, since the PRO has provided all the documentation on which it has based its recommendation, we believe that it is unnecessary for such discussion to occur prior to the OIG making a decision.

Section 1004.110—Notice of Sanction

Comment: Two commenters strongly opposed any alternative notification process for sanctions. One of the commenters indicated that an option of allowing the physician to notify privately both his or her existing and new patients does not adequately protect the public interest. While acknowledging the OIG's concerns that the current public notification may not be effectively reaching all of the physician's patients, the commenter stated that the same risk exists with

private notification and, therefore, suggested that private notification be mandatory and that it be used in addition to the current public notification process.

Response: We believe that the present public notification process has not yielded the most effective results of informing affected parties and program beneficiaries of a specific sanction action taken under the program. As a result of preliminary discussions with the AMA, the American Association of Retired Persons (AARP) and the Health Care Financing Administration, we believe that this approach, with built-in safeguards such as the certification of patient notice, would afford both the provider community and the patient community with an alternative for disseminating information regarding program sanctions. By definition, this alternative approach will offer a second options for public notification. Any effort to require both newspaper publication and direct notice to a physician's patients would, in effect, not offer an alternative as we have contemplated, but rather impose an additional layer of burden on the practitioner or other person. Our intent is for such notice to be both effective and cost-efficient, and we believe that this approach will meet those objectives. In addition, as indicated in the preamble to the proposed rule, where the OIG receives reliable evidence that a practitioner or other person has not adequately informed his, her or its new and existing patients of the sanction, the OIG reserves the right to follow existing procedures for public notification. Failure by the practitioner or other person to comply with the alternative method of notification once he, she or it has elected to do so will be adversely considered by the OIG at the time of application for reinstatement.

Comment: While supportive of the alternative notification process, two commenters requested that the regulations also include a requirement that the OIG receive a copy of the notice sent to each patient to determine its adequacy, or include in the regulations certain minimum requirements for the content of such notice. One commenter recommended that if providers are allowed to create their own letters, then it should be required that the letters be reviewed and approved first by the OIG prior to the provider sending them to the patients.

Response: We believe that the requirements that were set forth in proposed § 1004.110(d) with regard to patient notification and certification are adequate. As indicated, the OIG will

provide the sanctioned practitioner or other person a suggested model letter designed to address the nature of the sanction, as well as the exclusion's effective date and duration. In turn, the practitioner or other person is to specifically certify to the OIG that the information provided is truthful and accurate. Failure to properly inform one's patients and return to the required certification to the OIG within 30 days, or the obtaining of reliable evidence by the OIG that the practitioner or other person failed to adequately inform patients of the sanction, will result in the publication of a public notice and will be considered an aggravating factor at the time of the practitioner's or other person's application for reinstatement. As a result, we do not believe that the use of additional OIG staff time in reviewing such individuals letters is necessary.

Comment: In order to have each practitioner or other person in full compliance with the alternative notification approach, one commenter asked that the term "all existing patients" be cleared defined. In addition, the commenter questioned how notice to a new patient presenting himself or herself for emergency care would be handled, and whether such required notice would impede the provision or quality of care to such patients.

Response: We agree that the term "all existing patients" could be interpreted in different ways. In doing so, we believe it is necessary to balance our intent of assuring that proper notice is provided to the largest possible spectrum of program beneficiaries that may be affected by this sanction, without insurmountable burdens being placed on practitioners and other persons to contact their affected patient base. For this reason, we have agreed to define the term "all existing patients" to include all patients currently under active treatment with the practitioner or other person, as well as all patients who have been treated by the practitioner or other person within the last three years. We believe that this definition will provide adequate notification of the sanction to those most likely to be affected by it while assuring that this alternative approach remains a viable, effective option.

Patients being treated in an emergency situation could be notified verbally at the point they seek treatment, and since excluded physicians and others can be paid for emergency services, we do not believe this to result in a significant quality of care problem.