those sanctioned practitioners or other persons not electing this alternative method or failing to return the required certification form within the proposed 30-day period, the OIG would follow its standard procedure for public notification.

III. Response to the Public Comments

As a result of the proposed rulemaking published on February 28, 1994, the OIG received a total of 12 timely-filed public comments from various practitioners and providers, medical and professional associations, third party payers, peer review organizations and other interested parties.

Set forth below is a summary of those comments and our response to the issues and concerns raised.

Section 1004.1—Scope and Definitions

Comment: Three commenters stated that the term ''gross and flagrant'' was confusing, and as currently defined, has been erroneously interpreted to permit the Department and the PROs to focus on the outcome of the procedure and not on the degree of the violation. The commenters believed that under the existing definition the PROs have been given broad authority to arbitrarily determine that any given quality concern is potentially sanctionable, and that this, in turn, has lead to the initiation of the sanction process in some questionable cases.

Response: We believe it is important to retain the present definition and classification for the term ''gross and flagrant'' so that the severity of the violation can be demonstrated. While we have considered alternative definitions for defining this term, we believe that the current classification adequately and properly reflects the severity of the violation of the obligation(s) and the risk to the patient(s) which has already been identified. As to one commenter's suggestion that the patient must be ''harmed'' before a violation can be considered gross and flagrant, we disagree. We believe that a gross and flagrant violation includes those situations where a patient is placed in danger or in a high-risk situation, whether or not the patient is harmed. Thus, we are retaining the current definition.

Comment: While agreeing that there needs to be a definition for the term ''pattern of care,'' one commenter was concerned that the definition for ''substantial violation in a substantial number of cases''—which encompasses the requirement that there be an inappropriate pattern of care—has been interpreted to support a finding of a substantial violation exclusively on the basis of multiple allegations of treatment deficiencies in a single patient. The commenter believes this is unfair since, while a physician's course of treatment with respect to one patient may be alleged to be negligent, the treatment of a single individual does not indicate the ''pattern'' of professional negligence that the law was designed to address.

Response: We agree with the commenter's concern and have revised the definition of ''pattern of care'' in substantial violation cases to mean that the care under question has been demonstrated in more than 3 instances, which must involve different *admissions.* Under this revised definition, the instances could involve the same patient but reflect problems with the treatment occurring at different times. This is in contrast with the definition of gross and flagrant violations in which multiple violations may be found within the same admission.

Comment: One commenter objected to our defining the term ''practice area'' as ''the location where over 50 percent of the practitioner's or other person's patients are seen,'' and requested that the definition be deleted. The commenter believed that a practitioner who has *any* amount of practice in a rural area should be entitled to a preliminary hearing on the issue of whether that person's continued participation during the appeal of the exclusion would place program beneficiaries at serious risk.

Response: We are rejecting this comment since we believe it is not consistent with the statutory provision and congressional intent in providing for such preliminary hearings. If Congress wanted to extend the right to a preliminary hearing to *all,* or virtually all, practitioners and other persons, it would have done so in the statutory language. Rather, the statute and these regulations are targeted only to those who ''practice'' in a HPSA or a county with a population of less than 70,000, and not those who may occasionally see a patient in a rural area. In order to carry out the intent of the statutory provision, we believe that the definition for the term ''practice area'' is appropriate, fair and reasonable.

Section 1004.40—Action on Identification of a Violation

Comment: While several commenters strongly supported the OIG's proposal to eliminate the distinction between ''substantial'' violations and ''gross and flagrant'' violations, one commenter believed that the elimination of this distinction would result in less due process by removing the physician's right to receive two notices and two hearings for any violation.

Response: As noted in the proposed rule, the second meeting in substantial violation cases has proven simply to be a repeat of the initial or 20-day meeting. This, in turn, has increased the risk of serious patient harm due to this procedural delay. Experience has shown that this dual meeting process has tended to be cumbersome, time-consuming and confusing to both the physician responding to substantial violations issues and the physician members of the PRO's sanction panel. The OIG believes that this approach to eliminating the violations' distinction will serve program beneficiaries well while still continuing to provide adequate due process to all practitioners and other persons.

Comment: One commenter strongly agreed with the additional safeguards under § 1004.40 that state that the notice must contain information regarding the meeting, that an attorney may represent the practitioner, and that the attorney may make opening and closing remarks, ask clarifying questions at the meeting and assist the practitioner in presenting testimony of expert witnesses who may appear on behalf of the practitioner. However, the commenter believed that the notice should also contain a provision stating that the attorney may also cross-examine any physician or other expert who provided evidence upon which the PRO relied in identifying a potential violation under § 1004.10.

Response: We do not agree with the commenter's recommendation under § 1004.40 that notice should also include a provision that would allow attorney cross-examination. The meeting between the PRO and the practitioner or other person is not a formal adversarial hearing or trial. Rather, this meeting serves only as a medical dialogue to afford the practitioner or other person an opportunity to discuss medical issues.

Comment: Under § 1004.40, when a PRO identifies a violation, it must send a notice to the practitioner or provider identifying the specific concerns. One commenter stated that, while traditionally it has been up to the provider or practitioner to initiate a CAP before the PRO would consider it, this rule change places the obligation on the PRO to initiate resolution through a CAP. The commenter questioned whether the absence of a CAP in the notice constituted a determination by the PRO that the case cannot, at that