

October 30, 2000

June Gibbs Brown, Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Cohen Building, Room 5246  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: Office of Inspector General (OIG) Compliance Program for Individual and Small Group Physician Practices; *Federal Register* Vol. 65, No. 194, October 5, 2000**

Dear Inspector General Brown:

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM), representing 115,000 physicians who specialize in internal medicine and medical students, is pleased to provide comments on the final version of the “OIG Compliance Program for Individual and Small Group Physician Practices” published in the *Federal Register* on October 5, 2000. We also appreciated your staff’s September 25, 2000 briefing on how ACP–ASIM’s concerns and recommendations, detailed in our letter of July 26, 2000, were addressed in the final guidance. We are pleased to say that the vast bulk of ACP–ASIM’s recommendations were addressed in the final guidance, which should greatly increase its utility and acceptance in the physician community.

ACP–ASIM lauds the genuine effort expended by the Office of Inspector General (OIG) to improve upon its draft guidance, and to make it responsive to the needs and resource limitations of a solo or small group physician practice. In particular, we wish to express our appreciation for the following improvements which specifically addressed ACP–ASIM concerns and recommendations (as detailed in ACP–ASIM’s July 26, 2000 Letter to OIG on the Draft Compliance Guidance, provided as an Attachment).

***Recommendation A—Limit the length of the guidance to 5 or 10 pages.***

Action Taken by OIG: Although the final guidance’s length was not shortened, it was rewritten and reorganized in a manner that makes it much more readable and easy to use, meeting one of ACP–ASIM’s major underlying goals. Also, the final guidance added more options for physicians to meet compliance components, meeting another major College objective of offering maximum flexibility to physicians for implementing a compliance program.

***Recommendation B—Remove Reference to Federal Sentencing Guidelines.***

Action Taken by OIG: We appreciate OIG’s removal of all references to the Federal Sentencing Guidelines.

***Recommendation C—Reduce the complexity, legalistic tone, and unrealistic expectations for what a solo/small group physician practice can accomplish.***

Action Taken by OIG: The final guidance shows OIG made a major effort to soften the tone of the document, so that it is less legalistic and more attuned to a physician audience. This included removing reference to the Federal Sentencing Guidelines as noted, as well as removing the word “should” or “must” throughout the document, in place emphasizing the fact that compliance is voluntary, not mandatory.

Regarding the document’s complexity, the OIG has made it easier for physicians to understand which compliance program components and risk areas OIG considers most important by placing them in order of priority, and also offering more options and flexibility in how each component could be satisfied than provided in the draft guidance.

***Recommendation D—Emphasize the direct benefits of clearly demonstrable compliance—that it is good for patients and good for the business side of a medical practice.***

Action Taken by OIG: ACP–ASIM is very pleased with the OIG’s complete incorporation of this recommendation, stating that “patient care is, and should be, the first priority of a physician practice,” and that, “a practice’s focus on patient care can be enhanced by the adoption of a voluntary compliance plan.” The OIG then enumerates four other major benefits of a compliance program, stating “A well designed compliance program can:

- Speed and optimize proper payment of claims;
- Minimize billing mistakes;
- Reduce the chances that an audit will be conducted by HCFA or the OIG; and
- Avoid conflicts with self-referral and anti-kickback statutes.”

The OIG then reinforces these positive benefits by reiterating ACP–ASIM’s pro-active, problem-focused compliance philosophy: “Practices that embrace the active application of compliance principles in their practice culture and put efforts towards compliance on a continued basis can help to prevent problems from occurring in the future.”

***Recommendation E—Make clear that the “active application of compliance principles” is the ultimate indicator of a practice’s commitment to compliance, not the presence of a formalized, written compliance plan.***

Action Taken by OIG: As noted above, OIG has verbatim incorporated ACP–ASIM’s “active application of compliance principles” phraseology, and made clear that this carries much more weight than having a costly, formalized program that is not incorporated into the every day workings of a practice. The message to physicians, which the College supports, is that a practice need not do anything more than it already is, if it is not having difficulties in getting claims paid in a timely fashion and is not having problems with its carrier. This removes the burden implied by the draft guidance that a practice had to develop a written, formalized compliance program, and that it had to address all seven of OIG’s compliance elements (now renamed

“components”—see comments under Recommendation G, below) as OIG now leaves it up to the individual practice which components it wishes to address, and that none are considered mandatory or essential).

***Recommendation F—Encourage the development and use of self-diagnostic tools that physicians could use to direct and focus their compliance activities, as well as “fill-in-the-blank” templates which could be used to record and communicate compliance activities, corrective action plans, meetings with carrier staff, training, and other key elements of a well-designed compliance plan.***

Action Taken by OIG: In briefing our staff on September 25, 2000, ACP–ASIM was pleased to hear OIG state its strong support for medical associations’ development of self-diagnostic compliance tools for physicians, as requested in our July 26, 2000 comment letter. Though OIG staff indicated it would not be possible to create such “one-size-fits-all” templates as suggested above, we are pleased OIG has made clear that it does not expect or require physicians to address all seven compliance program components, and that a practice has the latitude to adopt only those components which experience indicates might be most helpful and productive.

***Recommendation G—Though ACP–ASIM feels the seven basic elements and risk areas in OIG’s draft guidance may have some merit, we believe physicians should have the option of adopting only those elements which, based on a practice’s real life history with billing problems and other compliance issues, are most likely to benefit from closer scrutiny and corrective/educational measures.***

Action Taken by OIG: ACP–ASIM appreciates the OIG’s addressing of this recommendation in the final guidance when it states: “Initial development of the compliance program can be focused on practice risk areas that have been problematic for the practice such as coding and billing. Within this area, the practice should examine its claims denial history or claims that have resulted in repeated overpayments, and identify and correct the most frequent sources of those denials or overpayments. A review of claim denials will help the practice scrutinize a significant risk area and improve its cash flow by submitting correct claims that will be paid the first time they are submitted. As this example illustrates, a compliance program for a physician practice often makes sound business sense.”

Also consistent with ACP–ASIM’s problem-focused compliance orientation, we are pleased that OIG has renamed its seven compliance elements as “components,” and indicated that physicians may choose which, if any, of these components are applicable to a practice in tailoring its own compliance effort. The section continues with a prioritized listing of the seven steps “a practice could take to begin development of a compliance program”—placing self-auditing and monitoring first, and which provide “numerous suggestions for implementation within each component”—exactly the type of flexibility ACP–ASIM has recommended.

***Recommendation H—*** Relating to the Draft Guidance Section “Application of Compliance Program Guidance”—***ACP–ASIM recommends that OIG make clear that inclusion of private payers in a compliance plan is completely optional, and that non-inclusion would not be***

***deemed an indication of general non-compliance, especially since OIG's jurisdictional authority only applies to payments made under federal health care programs.***

Action Taken by OIG: ACP-ASIM appreciates OIG's full incorporation of this recommendation in the final guidance, stating in its Introduction that its compliance guidance is for the purpose of promoting "adherence to statutes and regulations applicable to the Federal health care programs," (deleting "and private insurance program requirements" that was in the draft guidance). This is further supported by the addition of a new section in the final guidance entitled, "Scope of the Voluntary Compliance Program Guidance," which makes clear that the guidance only applies to Federal health programs and that any other use is optional: "This guidance focuses on voluntary compliance measures related to claims submitted to the Federal health care programs. Issues related to private payor claims may also be covered by a compliance plan if the physician practice so desires."

***Recommendation I— Relating to the Draft Guidance Section "Policy and Procedure Binder"-- ACP-ASIM recommends that the OIG and the Health Care Financing Administration (HCFA) should work together to develop a resource packet that would include governing federal laws, regulations, coverage criteria, carrier bulletins (including local medical review policies), and OIG compliance guidances and Special Fraud Alerts. The resource packet could be provided by HCFA or OIG, and updated on at least a yearly basis.***

Action Taken by OIG: At our September 25, 2000 meeting with OIG, ACP-ASIM was pleased to learn that HCFA and OIG are now working together to produce such a comprehensive resource packet for physicians. This resource packet should be available in the Fall of 2000 on both the HCFA and OIG websites, as well as by mail, and will be updated annually. We encourage OIG and HCFA to maximize distribution of this valuable resource compendium within the physician community.

***Recommendation J, Relating to the Draft Guidance Section, "Specific Risk Areas—Reasonable and Necessary Services"-- ACP-ASIM recommends that OIG (1) acknowledge that physicians must be free to act in the best interest of their patients, based on professional judgment and objective evidence of clinical effectiveness, when deciding on the appropriateness and necessity of services they provide or order for their patients and (2) that legitimate differences of opinions between physicians and Medicare reviewers on the medical necessity of a particular service does not place a physician at risk of violating fraud and abuse statutes.***

***The discussion of "reasonable and necessary" indicates that the physician has responsibility to keep current with OIG advisory bulletins. It is not realistic to expect that physicians will be able to obtain such information on their own, especially given the fact that many physician offices have limited access to the Internet.***

Action Taken by OIG: The OIG adequately addressed the core of this recommendation, revising final guidance language to make clear compliance only applies to the Medicare payment definition of "reasonable and necessary," and that professional judgement of what constitutes "reasonable and necessary" may diverge from this definition—"Medicare (and many insurance plans) may deny payment for a service that is not reasonable and necessary according to the

Medicare reimbursement rules. Thus, when a physician provides services to a Medicare beneficiary, he or she should only bill those services that meet the Medicare standard of being reasonable and necessary for the diagnosis and treatment of a patient. A physician practice can bill in order to receive a denial for services, but only if the denial is needed for reimbursement from the secondary payor.”

Regarding physician responsibility for keeping current with OIG advisory bulletins, OIG has addressed this by including this information in the comprehensive resource packet it is putting together with HCFA, as noted under Recommendation 4.

***Recommendation K***, Relating to the Draft Guidance Section “Designation of a Compliance Officer/Contact”--***ACP–ASIM urges OIG to remove its expectation that any member of a solo/small group practice who is assigned compliance responsibilities should be so independent as to be totally free of any conflicts of interest. This would preserve the option of using in-house staff to perform compliance duties, without having to outsource this function at added expense to the practice.***

***Another unrealistic expectation of the compliance officer/contact is that he/she ensure that all employees and physicians in the practice “know, and comply with, pertinent federal and state statutes, regulations, and standards.” It is highly unlikely any one person would “know” the vast domain of governing state and federal requirements, and even less likely that he/she could ensure that everyone else in the practice knew and complied with same. In this regard, ACP-ASIM recommends that the OIG should make its expectation regarding the role of the compliance office/contact more realistic, by changing the above wording to: “ensuring that employees and physicians in the practice are aware of, and strive to comply with, pertinent federal and state statutes, regulations, and standards.”***

**Action Taken by OIG:** ACP–ASIM appreciates OIG’s full incorporation of this recommendation through a major rewriting of this section in the final guidance. The revised section intrinsically acknowledges that, with small staffs and limited resources, practices must utilize whatever staff they have to perform compliance functions, removing draft guidance language that “the person be sufficiently independent in his or her position so as to protect against any conflicts of interest...” The revised section also acknowledges that “the resource constraints of physician practices make it so that it is often impossible to designate one person to be in charge of compliance functions,” instead allowing for this responsibility could be dispersed among one or more practice employee “compliance contacts,” another possibility being “one individual could serve as compliance officer for more than one entity,” and another option permitting the practice to “outsource all or part of the functions of a compliance officer to a third party...”

The final guidance also provides helpful clarification of which specific compliance functions (such as training and education) may be outsourced with different types of third parties, such as a hospital’s compliance program, and those which would be better to retain in-house. In the OIG’s words (p.6), “The opportunities for collaborative compliance efforts could include participating in training and education programs or using another entity’s policies and procedures as a template from which the physician practice creates its own version. The OIG encourages this

type of collaborative effort, where the content is appropriate to the setting involved (i.e., the training is relevant to physician practices as well as the sponsoring provider), because it provides a means to promote the desired objective without imposing excessive burdens on the practice or requiring physicians to undertake duplicative action.”

Addressing ACP–ASIM’s concern that the OIG’s expectations for a compliance officer’s range of control over other practice staff is unrealistic, the OIG has eliminated the draft guidance language which held the compliance officer accountable for “ensuring that employees and physicians know, and comply, pertinent Federal and State statutes, regulations, and standards.”

**Recommendation L**, Relating to Draft Guidance Section “Conducting Effective Training and Education”--*ACP-ASIM recommends that the OIG should revise this section to recognize the practical limitations on the ability of smaller physician practices to institute formal training and education programs for employees. The OIG should also eliminate inconsistencies in the guidance (such as on whether or not posting of information on a bulletin board is sufficient), and acknowledge that most physician practices do not employ a trained coder.*

Action Taken by OIG: ACP–ASIM is pleased with OIG’s complete addressing of this recommendation, by renaming this section of the final guidance, and revising its content so as to give practices maximum flexibility in determining what training is needed by staff (based on identified problems and needs), and how training and dissemination of compliance information is accomplished.

The last of the above ACP–ASIM concerns, that OIG acknowledge that most physician practices do not employ a trained coder, is addressed in the final guidance with the following added language: “The OIG understands that most physician practices do not employ a professional coder and that the physician is often responsible for all coding and billing.”

### **ACP–ASIM Recommendations Not Fully Addressed in the Final Guidance**

ACP–ASIM appreciates OIG’s statement, made at our September 25, 2000 meeting, that it considers the guidance a “work-in-progress” which it is willing to improve upon based upon input from physicians who attempt to apply OIG’s compliance components in the field. In this spirit, we would like to reiterate recommendations contained in our July 26, 2000 letter which were not fully addressed:

**Recommendation A**, Relating to Draft Guidance Section “Auditing and Monitoring”-- : *ACP-ASIM strongly urges OIG and HCFA to require and ensure a much higher level of carrier accountability and responsiveness to physician inquiries regarding claims and coding requirements. HCFA’s goal of establishing carrier 800 numbers physicians can call into for assistance is a step in the right direction. We also recommend that carriers be required to offer physicians the opportunity to meet and rectify billing irregularities identified by the carrier before an audit by the carrier, or a referral to OIG by the carrier, is initiated (with the exception of flagrant instances of fraud).*

Action Taken by OIG: At our September 25, 2000 meeting with OIG, OIG acknowledged that the vast bulk of physicians' claim problems could be dealt with and rectified at the level of the Medicare carrier, but that an initiative to improve physician-carrier communications is the responsibility of HCFA. Thus, the final guidance does not really address the above concerns. However, it was acknowledged by both parties that HCFA is taking steps to improve physician-carrier relations and communications, with the establishment of the above mentioned carrier 800 numbers for providers, and a recent HCFA Program Memorandum to carriers, effective October 1, 2000, which institutes a "Progressive Corrective Action" program which requires carriers to be more discriminating and less intrusive in its physician claims review activities, and to inform physicians when they are being put on pre- or post-payment review by carriers. We would urge OIG to work with and encourage HCFA to be aggressive about continuous improvement of the carrier-physician interface, as the quality of this relationship and related communications lies at the heart of so many compliance issues.

**Recommendation B**, Relating to Draft Guidance Section "Enforcing Standards Through Well-Publicized Disciplinary Guidelines,"--***ACP-ASIM is concerned with OIG's statement that "The program should also stipulate that individuals who fail to detect or report violations of the compliance program may also be subject to discipline. ACP-ASIM recommends that OIG limit the above statement so that it applies only to those who fail to report known violations of the compliance program.***

Action Taken by OIG: OIG did not fully satisfy this recommendation, leaving in the word "detect" but softening the overall importance of this requirement in a practice's overall compliance program. This was accomplished by placing this component last in among the 7 compliance component priorities, and suggesting this disciplinary policy as a possible rather than required compliance program element. ACP-ASIM still feels strongly that "failure to detect" instances of possible non-compliance is an unrealistic expectation and burden placed upon individuals in a practice, and that this requirement, as well as linking it to disciplinary action, should be deleted.

**Recommendation C**, Relating to Draft Guidance Section "Responding to Detected Offenses and Developing Corrective Action Initiatives,"--***ACP-ASIM recommends that OIG revise the wording under this compliance program element to make it clear that self-disclosure, even if done in good faith and in accord with OIG's Provider Self-Disclosure Protocol, does not provide immunity from auditing/adverse action from other sources, such as carriers and the Department of Justice, and that consultation with counsel prior to self-disclosure is advisable in such matters.***

Action Taken by OIG: This recommendation is not adequately addressed in the final guidance; it does not make clear that following OIG's Provider Self-Disclosure Protocol does not provide immunity from auditing/adverse action from other sources. Although there is a footnote that recommends consultation with an attorney in instances of possible non-compliance, ACP-ASIM still would urge OIG to explicitly state that no immunity is implied when a provider self-discloses.

## **Conclusion**

OIG has made a concerted effort to make its final physician compliance guidance one that is attuned to a physician audience, free of legalistic jargon, non-threatening, easy to use, problem-focused, flexible, and considerate of limited practice time and resources. ACP-ASIM commends OIG's considerable effort and final product, and appreciates the OIG's willingness to listen to and accommodate the physician's voice through an open and ongoing dialogue with physicians and staff of the College. We look forward to our continuing, productive work with the OIG, and commend the substantial progress and symbol of collaboration the final guidance so ably represents.

Please direct any questions or concerns related to this correspondence to Mark Gorden, Senior Associate for Managed Care and Regulatory Affairs at (202) 261-4544.

Sincerely,

Cecil B. Wilson, MD, FACP  
Chair  
Medical Services Committee

Attachment



## ATTACHMENT

July 26, 2000

June Gibbs Brown, Inspector General  
Office of Inspector General  
Department of Health and Human Services  
Attention: OIG-7P-CPG  
Room 5246  
Cohen Building  
330 Independence Avenue, S.W.  
Washington, D.C. 20201

**RE: Draft OIG Compliance Program for Individual and Small Group Physician Practices; OIG-7P-CPG; 65 *Federal Register* 36818 (June 12, 2000)**

Dear Inspector General Brown:

The American College of Physicians–American Society of Internal Medicine (ACP–ASIM), representing 115,000 physicians who specialize in internal medicine and medical students, is pleased to provide comments on the “Draft Office of Inspector General (OIG) Compliance Program for Individual and Small Group Physician Practices” published in the *Federal Register* on June 12, 2000. We also appreciate the opportunity to provide our input in person when we meet with OIG staff on July 27, 2000, continuing the collaborative and open dialogue between OIG and ACP–ASIM begun in May of 1999.

### **General Comments on OIG’s Draft Compliance Guidance**

ACP–ASIM commends OIG’s efforts to incorporate some of our recommendations for a physician compliance guidance contained in our November 8, 1999 letter (which responded to the September 8, 1999 OIG *Federal Register* solicitation for suggestions for such a guidance). We recognize that the OIG has made a good faith effort to recognize that an effective compliance guidance for physicians must take into account the limited resources available to physicians in small group and solo practices available to institute a compliance plan. The compliance guidance appropriately proposes a variety of options for physicians to consider in instituting a compliance plan, rather than mandating a “one size fits all” approach. We are pleased that the OIG includes options for meeting the seven basic compliance plan elements. We are also pleased that the OIG incorporated our recommendation to specify key risk areas that the OIG is most interested in having physicians monitor. ACP-ASIM is also pleased that the compliance guidance clearly states OIG’s belief that most physicians are honest practitioners that are committed to doing what is right for their patients and the Medicare program.

However, we are disappointed OIG did not fulfill our leading recommendations for a guidance--that it be kept to five or ten pages and substantially depart from OIG's other industry guidances, especially in removing its use of the Federal Sentencing Guidelines. The inclusion of the Federal Sentencing Guidelines will have a strong negative connotation for most physicians, one which will seem to be at odds with the OIG's expressed commitment to working constructively with physicians to reduce fraud and abuse rather than emphasizing punitive sanctions.

Issuance of a compliance guidance will be of little value if not accepted and applied in the physician community. Unfortunately, we believe that without substantial improvements in several key areas, the draft guidance has little chance of such acceptance, due to its length, complexity, legalistic tone, and unrealistic expectations for what a solo/small group physician practice can accomplish. We are concerned that many physicians will likely view the guidance as being overly complex and intimidating. It is likely to heighten their fears of increasing governmental intrusion in the practice of medicine and more OIG physician audits, driving away the very audience for which it was intended.

It is hard for physicians to believe that they can "voluntarily" ignore 43 pages of OIG rules, laws, and guidance. Physicians are left in the dark trying to divine what OIG means when it says they must have an "effective compliance plan," since this is not defined in the draft guidance. Physicians are asked to take on what could be a substantial investment in time, money, and resources—for the somewhat faint benefit that, in the rare contingency of an OIG audit, existence of such a plan would be considered a "mitigating circumstance."

Considering the voluntary nature of a compliance plan, and its potential to take valuable time away from direct patient care, the benefits of implementing a compliance plan must be made more compelling. Physicians need to know how their patients and their practices will benefit from voluntary participation in a compliance program. Instead of being perceived as another regulatory burden, a compliance plan should be seen as a useful business and professional ally. ACP-ASIM believes the compliance guidance should:

- Emphasize the direct benefits of clearly demonstrable compliance—that it is good for patients *and* good for the business side of medical practice: i.e. a well-designed compliance program can speed and optimize proper payment of claims, minimize billing mistakes, free up more physician time for patient care, avoid conflicts with self-referral/kickback statutes, and reduce the chances that an audit from HCFA or the OIG will ever occur.
- Make clear that the *active application of compliance principles* is the ultimate indicator of a practice's commitment to compliance, *not* the presence of a formalized, written compliance plan.
- Encourage the development and use of self-diagnostic tools that physicians could use to direct and focus their compliance activities, as well as "fill-in-the-blank" templates which could be used to record and communicate compliance activities, corrective action plans, meetings with carrier staff, training, and other key elements of a well-designed compliance plan. The OIG should encourage the development of such tools and

templates by professional associations and other physician advisors, and provide the OIG's assistance, input and ultimate "seal of approval" as such products are being developed and implemented. Physicians need to be assured that the OIG will accept the use of self-diagnostic tools and "fill-in-the-blank" templates as a reasonable response to the seven key elements, and professional associations must have similar assurances before they will commit to developing such products. Though ACP-ASIM feels the seven basic elements and risk areas in OIG's draft guidance may have some merit, we believe physicians should have the option of adopting only those elements which, based on a practice's real life history with billing problems and other compliance issues, are most likely to benefit from closer scrutiny and corrective/educational measures.

ACP-ASIM recognizes that implementing the above recommendations will require that the OIG re-evaluate how the information in the compliance guidance is presented to physicians, as well as necessitate changes in specific sections of the compliance guidance as discussed below. As always, we stand ready to work closely with OIG to design the type of guidance suggested above, one that makes good business practices and compliance synonymous.

**Specific Comments on OIG's Draft Compliance Guidance** (lettered/numbered as items appear in the draft OIG guidance. ACP-ASIM is commenting only on a subset of the lettered/numbered items in the draft guidance; those for which we have no specific comments are excluded from the following discussion).

ACP-ASIM believes that many of the recommended practices in the draft compliance guidance are simply good business practices that could be adhered to with a reasonable level of effort, even by small practices. Codes of conduct, mission statements, periodic chart audits and clear procedures for employees with concerns or questions would not be terribly burdensome. That said, codifying the process of submitting claims, reviewing explanation of benefit forms for denials and correcting claims with a goal of total compliance for all payers is not feasible for small practices. Our specific comments are as follows:

## **I. Introduction**

### **A. Benefits of a Compliance Program**

OIG states that one benefit of a compliance program is to "further the mission of all physician practices to provide quality care to their patients." Our concern is that the opposite could occur—that patient care could suffer if a practice spent too much of its time trying to fulfill what it perceives OIG's expectations to be regarding compliance at the expense of devoting less time toward care of patients.

*Recommendation:* ACP-ASIM recommends that the OIG explicitly acknowledge that patient care must be the first priority of a practice, and that the effort expended on compliance activities must not be at the expense of patient care.

### **B. Application of Compliance Program Guidance**

OIG states that a compliance plan should apply for all payers, not just Medicare. Though we understand this conceptually, practically this would greatly multiply a practice's level of effort and possibly dilute its effectiveness in monitoring Medicare compliance.

*Recommendation:* ACP-ASIM recommends that OIG make clear that inclusion of private payers in a compliance plan is completely optional, and that non-inclusion would not be deemed an indication of general non-compliance, especially since OIG's jurisdictional authority only applies to payments made under federal health care programs.

## **II. Compliance Program Elements**

### **A. The Seven Basic Compliance Elements**

OIG's suggestion that physician practices participate in other healthcare providers' compliance programs, such as those of local hospitals, might be difficult for a number of reasons. One reason would be the technical complexity of trying to integrate the compliance activities of a large institution and a small practice. Some local hospitals might not be willing to extend this level of additional effort, while others might consider such integration intrusive. Also, in some rural areas, there may simply not be any hospitals or other entities to which physicians can link their compliance activities.

*Recommendation:* ACP-ASIM recommends that the OIG should acknowledge the technical difficulties involved in integrating physician practices into compliance programs offered by other institutions.

### **B. Written Policies and Procedures**

This section does not clearly indicate the suggested requirements. Page 7 suggests that this requirement would be met by a two step plan including a compliance manual and up to date forms for coding and documentation. However, under Specific Risk Areas, Coding and Billing (Page 8), this is expanded to also include policies for coding and billing and review of denials regardless of payer. Trying to create a compliance plan to meet multiple payers requirements, as well as Medicare requirements is not feasible. Typical practices will have two to four bookshelves of Medicare and other payer documentation, with anywhere from 4-8" of documents per plan. Creating a detailed procedure to avoid all "incorrect" billings is not possible. Different payers may also have conflicting billing or coding policies, which further complicates compliance efforts.

*Recommendation:* ACP-ASIM recommends that the OIG should revise this section to recognize that creation of a detailed procedure to avoid all "incorrect" billings is not feasible for the typical physician practice.

### **2. Policy and Procedure Binder**

ACP-ASIM supports the concept of maintaining written policies and procedures concerning code of conduct, billing and coding, patient care, documentation, payer relationships, and OIG

identified risk areas and related laws. However, the massive effort to gather all this information, keep it up to date, and be thoroughly aware of every requirement, would be daunting if not impossible.

*Recommendation:* ACP-ASIM recommends that the OIG and the Health Care Financing Administration (HCFA) should work together to develop a resource packet that would include governing federal laws, regulations, coverage criteria, carrier bulletins (including local medical review policies), and OIG compliance guidances and Special Fraud Alerts. The resource packet could be provided by HCFA or OIG, and updated on at least a yearly basis. This would not only save an enormous amount of time, but also be particularly helpful to those physicians who still do not have access to the Internet. As such, ACP-ASIM recommends that HCFA and/or OIG provide such a binder, along with regular updates, to physicians free of charge, therein freeing up more time for patient care and compliance activities.

### 3. Specific Risk Areas

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Regarding the four major risk areas identified by OIG, ACP-ASIM has concerns about the inclusion of “Reasonable and Necessary Services” as one of the four risk areas requiring greater physician scrutiny. Physicians must be free to act in the best interest of their patients, based on professional judgment and objective evidence of clinical effectiveness, when deciding on the appropriateness and necessity of services they provide or order for their patients. There will be instances when a physician’s professional judgment on what constitutes reasonable and necessary care is not congruent with Medicare’s definition or the judgement of a particular Medicare carrier reviewer. Such instances should not automatically be considered a form of non-compliance, and should only be a concern if a pattern of regular and willful divergence from Medicare criteria is established. ACP-ASIM agrees, however, that the rare health care professional that engages in a consistent and willful pattern of decision-making, which results in patients getting unnecessary, inappropriate, and ineffective services, is at risk of being audited and potentially found to be in violation of fraud and abuse statutes. However, we expect that physicians who willfully engage in such activities are unlikely to be deterred by the OIG’s compliance guidance, since it is honest physicians that are the ones who are most likely to voluntarily institute a compliance plan for their practices.

*Recommendation:* ACP-ASIM recommends that OIG (1) acknowledge that physicians must be free to act in the best interest of their patients, based on professional judgment and objective evidence of clinical effectiveness, when deciding on the appropriateness and necessity of services they provide or order for their patients and (2) that legitimate differences of opinions between physicians and Medicare reviewers on the medical necessity of a particular service does not place a physician at risk of violating fraud and abuse statutes.

The discussion of “reasonable and necessary” indicates that the physician has responsibility to keep current with OIG advisory bulletins. It is not realistic to expect that physicians will be able to obtain such information on their own, especially given the fact that many physician offices have limited access to the Internet.

*Recommendation:* ACP-ASIM recommends that this either be deleted or a requirement included that information be made readily available through carrier advisory bulletins or through a regularly updated resource packet from HCFA and the OIG that would include governing federal laws, regulations, coverage criteria, carrier bulletins (including local medical review policies), and OIG compliance guidances and Special Fraud Alerts, as discussed earlier.

#### C. Designation of a Compliance Officer/Contact

OIG has recognized the impracticality of a solo/small group practice hiring a full time compliance officer, and has offered a number of options, which appear reasonable, such as making this a part-time responsibility of one of the practice's staff, such as the office manager or the primary biller. However, OIG's expectation "that the person be sufficiently independent in his or her position so as to protect against any conflicts of interest that may arise from performing assigned duties and compliance duties" is unreasonable. By virtue of being either the primary biller or office manager, this person would work directly in the major risk areas already identified by OIG (e.g., coding and billing, business relationships with other entities). Expecting that they avoid "any conflicts of interest" is an unrealistic expectation on OIG's part.

*Recommendation:* ACP-ASIM urges OIG to remove its expectation that any member of a solo/small group practice who is assigned compliance responsibilities should be so independent as to be totally free of any conflicts of interest. This would preserve the option of using in-house staff to perform compliance duties, without having to outsource this function at added expense to the practice.

Another unrealistic expectation of the compliance officer/contact is that he/she ensure that all employees and physicians in the practice "know, and comply with, pertinent federal and state statutes, regulations, and standards." It is highly unlikely any one person would "know" the vast domain of governing state and federal requirements, and even less likely that he/she could ensure that everyone else in the practice knew and complied with same.

*Recommendation:* ACP-ASIM recommends that the OIG should make its expectation regarding the role of the compliance office/contact more realistic, by changing the above wording to: "ensuring that employees and physicians in the practice are aware of, and strive to comply with, pertinent federal and state statutes, regulations, and standards."

#### D. Conducting Effective Training and Education

This section sets out contradictory standards which need to be resolved; i.e. it states that posting of information on a bulletin board or in a newsletter is sufficient, but the next sentence indicates that providing information for an individual to read on their own is not sufficient (page 12.) The assumption that small practices employ coders is false. Physicians typically code their own encounters. The OIG also needs to recognize that often a billing employee will leave and not be available to train a new staff member for any extensive period of time. Physicians in rural areas will have limited access to off-site training and may be forced into on the job training when the sole biller leaves and does not allow sufficient overlap with the replacement staff member.

Frequently a good portion of training is "on the job" with the employee correcting claims errors after the fact.

*Recommendation:* ACP-ASIM recommends that the OIG should revise this section to recognize the practical limitations on the ability of smaller physician practices to institute formal training and education programs for employees. The OIG should also eliminate inconsistencies in the guidance (such as on whether or not posting of information on a bulletin board is sufficient), and acknowledge that most physician practices do not employ a trained coder.

#### F. Auditing and Monitoring

- ACP-ASIM feels effective auditing and monitoring, linked to timely remedial action and educational feedback to practice staff, is the heart of a successful compliance program. Crucial to auditing and monitoring is having open and direct lines of communication with carrier staff, so that practices can quickly learn and correct billing problems that cause claims to be rejected.

Unfortunately, guidance on billing and coding requirements from carriers, and even within the same carrier, can often be inconsistent, while accessing carrier staff for information/advice is frequently difficult and time consuming. If physicians do not have clear and accurate information on why claims are being rejected, they cannot implement the appropriate corrective/educational measures needed to eliminate the problem. Thus, the value of a practice's auditing and monitoring function can be no better than the quality and timeliness of information received from its carriers, and the commitment of the practice to utilize such feedback to optimize compliance.

*Recommendation:* ACP-ASIM strongly urges OIG and HCFA to require and ensure a much higher level of carrier accountability and responsiveness to physician inquiries regarding claims and coding requirements. HCFA's goal of establishing carrier 800 numbers physicians can call into for assistance is a step in the right direction. We also recommend that carriers be required to offer physicians the opportunity to meet and rectify billing irregularities identified by the carrier **before** an audit by the carrier, or a referral to OIG by the carrier, is initiated (with the exception of flagrant instances of fraud).

#### G. Enforcing Standards Through Well-Publicized Disciplinary Guidelines

- ACP-ASIM believes employees must be well informed of the consequences of intentional non-compliant conduct, and that a practice must be willing to take disciplinary action if its compliance program is to have teeth. We are concerned with OIG's statement that "The program should also stipulate that individuals who fail to detect or report violations of the compliance program may also be subject to discipline." Our concern is that this standard may be a bit severe for an employee who fails to detect a compliance violation, as opposed to an employee who is aware of such a violation and fails to report it.

*Recommendation:* ACP-ASIM recommends that OIG limit the above statement so that it applies only to those who fail to report known violations of the compliance program.

## H. Responding to Detected Offenses and Developing Corrective Action Initiatives

ACP–ASIM is concerned that physicians may be led into believing that good faith self-disclosure of possible or known compliance errors provides blanket protection against adverse action. In truth, self-disclosure does not provide the protection that may be implied by the OIG draft guidance, as physicians may be subject to pre- and post-payment carrier audits, investigation by enforcement agencies other than OIG, discovery procedures initiated by a third party, and *Qui tam* actions.

*Recommendation:* ACP–ASIM recommends that OIG revise the wording under this compliance program element to make it clear that self-disclosure, even if done in good faith and in accord with OIG’s Provider Self-Disclosure Protocol, does not provide immunity from auditing/adverse action from other sources, such as carriers and the Department of Justice, and that consultation with counsel prior to self-disclosure is advisable in such matters.

### **Conclusion**

ACP–ASIM commends OIG’s efforts to help guide physicians in the development of individual and small group practice compliance plans. However, in order for such a guidance to have impact, it must have widespread appeal and acceptance in the medical community. This translates into a guidance which is short, easy to use, has obvious and direct professional benefits (such as freeing up more time for patient care), and which is mindful of the limited time and resources of the target audience.

Unfortunately, OIG’s draft physician guidance is too long and legalistically oriented to be put into practical use by the solo/small group physician. The draft guidance is more conceptual than hands-on, forcing physicians to guess what comprises an “effective” compliance plan, creating anxiety that whatever they develop will not be good enough. Considering the fact that implementing a compliance plan is voluntary and all the effort and expense this might involve, its possible mitigating value in the rare event of an OIG audit is not likely to offer sufficient incentive to pursue such an undertaking.

At the level of the individual/small group practice, physicians need ready-made, adaptable tools they can use to assess their compliance risk areas, and to help them bring focus to their compliance activities. ACP–ASIM looks forward to continuing to work with the OIG to develop a compliance program which physicians will use because they find it helpful in their practices.

Please direct any comments or questions you may have concerning this correspondence to Mark Gorden, Senior Associate for Managed Care and Regulatory Affairs, at (202) 261-4544.

Sincerely,

Cecil B. Wilson, MD, FACP



Chair  
Medical Services Committee