Testimony of
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Good morning, I am George Grob, Deputy Inspector General for Evaluation and Inspections in the Office of Inspector General (OIG), Department of Health and Human Services. Thank you for the opportunity to address the Committee on Small Business regarding the regulatory burden on small health care providers. You asked us for our views on what administrative changes can be made in the operation of the Medicare program without compromising program integrity. We appreciate the opportunity to share our ideas on this subject with you.

This is an extremely important issue, but one that is also complex and defies quick fixes. As such, it must be addressed at several different levels, and it will require the attention and concerted efforts of all of us--providers, program managers, oversight and law enforcement officials, and the Congress--to find manageable and efficient solutions. I hope that my testimony plays a constructive and helpful role in that respect.

I will offer principles and a framework for addressing the issue of regulatory burden; identify some related infrastructure issues that need to be addressed; and discuss education and outreach to health care providers. As you requested, I will also discuss H.R. 868, the Medicare Education and Regulatory Fairness Act of 2001 and some of its implications for program integrity and burden on providers. Finally, I would like to make some observations about providers' concerns about oversight activities in general.

## General Principles

First, let me state the obvious: Medicare is one of our most cherished governmental programs. It provides excellent, quality health care coverage to almost 40 million aged and disabled Americans. It provides insurance coverage to a population that historically has had great difficulty in obtaining insurance. Because of the vast amounts of money involved (in excess of $220 billion annually), there are significant vulnerabilities to fraud, waste, and abuse. But concern regarding these issues must not overly interfere with the mission of the program to provide high quality, timely health care to eligible beneficiaries.

Therefore, I would suggest to you that what is needed above all is balance--balance among meeting beneficiaries' needs, protecting the financial viability of the program, and minimizing burdens placed on providers. Only by focusing on all three can we run an effective program that meets the expectations of all involved.

### *Meeting Beneficiaries' Needs*

Medicare beneficiaries have a right to expect high quality, timely health care. Reimbursement should be sufficient to encourage adequate provider participation to ensure access to covered services. Beneficiaries should feel confident that they are obtaining services from legitimate providers and ones that are in compliance with State and Federal licensure and certification requirements. They should

not be subjected to onerous paperwork or other regulatory burdens. Finally, they should be able to obtain timely, understandable information regarding their benefits and health care choices.

*Protecting Financial Integrity*

Another paramount principle is the protection of the financial viability of the Medicare trust funds. Medicare is funded both by taxes paid by participants (and their employers) as well as revenue from the general treasury. We have an obligation to protect the financial viability of the trust funds so that the program is there for future generations.

*Burdens on Providers*

The vast majority of health care providers are honest, hard working professionals dedicated to the care of their patients. They have legitimate concerns about program complexity, inconsistency, burdens, and hassles associated with the Medicare program. Providers need to be able to do what they were trained to do--deliver health care--and not be subject to unreasonable regulatory or administrative burdens. Their concerns deserve careful consideration.

## Infrastructure

Keeping in mind the broad principles discussed above, we can now drop down one level to begin focusing on the practical mechanics of program operations. First, we must consider the broad contours of Medicare administration--the infrastructure. No matter how much attention is paid to the details of regulations and relationships, they cannot possibly work if the broad systems upon which they depend do not function effectively, efficiently, and seamlessly. Of critical importance are Medicare contractors and the appeals system.

*Contractors*

We believe that Medicare needs greater flexibility in the methods it uses to select, organize, and supervise the contractors who handle the day-to-day operations of the program. This includes authorities to use entities other than insurance companies, select them competitively, pay them on other than a cost basis, organize them according to functions or benefits areas, and hold them accountable for performance.

CMS administers the Medicare program with the help of approximately 50 contractors (Part A intermediaries and Part B carriers) that handle claims processing and certain payment safeguard functions. Over the years we have detected serious problems with contractor operations, including fundamental problems with accounting, electronic data processing, and fraud control. We have even uncovered integrity problems with some of the contractors themselves--altering documents and falsifying statements that specific work was performed. In some cases, contractors prepared bogus documents to demonstrate superior performance, which Medicare then rewarded with bonuses and additional contracts. Our investigations have resulted in 15 civil settlements and criminal convictions since 1993, with total settlement amounts exceeding $350 million. Two contractors pled guilty to obstruction of Federal audits. A number of investigations are ongoing. CMS has been working to correct problems with contractors. However, some serious concerns remain.

Under the Health Insurance Portability and Accountability Act of 1996 (HIPPA), CMS was granted new authorities and flexibility in contracting for program integrity functions. It may enter into contracts or work orders for specific program safeguard functions, such as medical review, fraud detection, cost report audits, and reviews to identify primary payers to whom Medicare is the secondary payer. We have consistently supported these authorities and look forward to the changes in Medicare contracting that are taking place under the new Medicare Integrity Program.

In contrast to these new and promising developments for integrity functions, the Medicare statute places substantial limits on how CMS obtains contractor assistance to administer the Medicare program. For example, it limits CMS to choosing only insurance companies to process Part B claims. Similarly, most intermediaries are selected by the National Blue Cross/Blue Shield Association companies that are nominated by providers (e.g., hospitals). All contracts must be cost based; other reimbursement methods such as firm fixed price cannot be used. Furthermore, beyond the program integrity functions mentioned above, CMS is not allowed to let contractors specialize according to function.

No modern corporation could or would operate with similar limitations. Medicare, the world's largest health insurance program, should not have to either. While these legal structures might have made sense as a way to quickly muster structures, processes, and expertise when the program was first enacted, they are no longer appropriate.

CMS has proposed broader, more flexible contracting authority in the past, but these proposals were not approved. We have supported such proposals in past congressional testimony, and we continue to do so. So does the General Accounting Office.

Another promising development is the designation of specialty contractors such as the durable medical equipment regional carriers. They review and pay all claims for medical equipment and supplies. There are only four of them, which appropriately concentrates their expertise in this complex area. They are bolstered by a data analysis unit, staffed by one of these carriers but supporting them all. This enables them to analyze payment and usage patterns, which may suggest possible improper or questionable conduct. They are also able to effectively collaborate on the formulation of national coverage policies and payment control systems. A recent OIG evaluation found that these entities were successful at meeting their intended objectives. This approach, however, has not been used elsewhere, except for home health and hospice care. However, even these specialized intermediaries are not supported by the kind of data analysis unit that the medical equipment carriers utilize. We believe that specialty contractors, with a supporting analytic unit, would make sense for problematic areas and recommend that they be more widely used.

More flexibility and specialization will, we believe, bring greater expertise and efficiency to contractor operations. Providers have fewer entities to deal with; medical review and utilization parameters are more standardized; information is dispensed more consistently. All of this can improve their relations with providers and facilitate provider education and understanding of Medicare rules and regulations.

*Appeals*

An OIG report released in September 1998 examined the ALJ appeals level because of numerous reports of extensive problems in and related to that area. The report established that the number of Part B ALJ hearings increased a dramatic 99 percent from 1996 to 1998. It also confirmed that ALJs reversed a considerable percentage of cases that reached them. An important reason for the reversals was that ALJs are not bound by the same standards as carrier hearing officers. More specifically, carrier hearing officers are bound by Local Medical Review Policy and contractor manuals, while the ALJs are bound only by statute, regulations and National Coverage Determinations.

There was also evidence of positive changes in the appeals process. The report identified a group of SSA ALJs who conduct the most complex and highest dollar value Part B cases. It was their work, in part, that supported our conclusion that a permanent cadre of judges hearing only Medicare cases would significantly improve the appeals system.

We made several recommendations to CMS intended to correct the structural problems of the administrative appeals system which were related to the development and establishment of: a dedicated ALJ corps, dual administrative appeals processes for providers and beneficiaries; adversarial hearings for provider appeals; parallel training for Medicare contractors and ALJs; regulations for conducting Medicare ALJ Appeals; a case precedent system for Medicare Appeals Council rulings; and formal communication and information networks. We also recommended requiring Medicare contractors and ALJs to apply the same standards. Although many of these recommendations would lead to a simpler and more efficient process, to date, none of these recommendations has been implemented.

The recently enacted Benefits Improvement and Protection Act of 2000 (BIPA) modified the appeals process by establishing time limits on earlier stages of the appeals process which, if breached, give the appellant the option to move to the next higher level. These new provisions, which will go into effect on October 1, 2002, could lead to inappropriate decisions due to unrealistic time spans to address complex questions, a clogging of the appeals channels, and an inability to prioritize decision making.

The BIPA provisions were intended to address legitimate concerns of providers to get prompt answers to their appeals and coverage questions. However, some of these new procedures are likely to cause additional rather than fewer burdens and aggravations by overwhelming the appeals and review channels. Furthermore, they do not address the weaknesses in the fundamentals of the appeals and grievance systems--resources, guidance and standards, organizational locus of ALJs, rules of precedence, appropriate adaptation of procedures to beneficiaries and providers, and timeliness of reviews. We believe it is time for a comprehensive reform of the appeals system, considering input from all the affected parties. Some improvements can be made through administrative actions under the current statutes; but fundamental reform may require, and could well benefit from, new legislation. This could be accomplished while preserving the ideas, and even many of the procedural details, of the BIPA amendments.

## Outreach and Education

Far and away, the best way to both protect the financial integrity of the Medicare program and reduce provider burdens is to reduce payment errors. Health care providers have been strong in their desire for training and education that will help them understand Medicare rules and regulations.

Training of health care providers is properly the responsibility of CMS and Medicare intermediaries and carriers. The OIG has frequently made recommendations to CMS to provide additional training on matters that we have discovered to be problematic in our audits and evaluations. The need for continuing training is prominent in the recommendations that we have made in our payment error rate study in each of the last several years. Specifically, we have recommended that CMS continue to:

- direct that Medicare contractors expand provider training to further emphasize the need to maintain medical records containing sufficient documentation, as well as to use proper procedure codes when billing Medicare for services provided;

- highlight to Medicare providers specific procedure codes and DRGs having the highest incidence of error in our audits, as well as those codes and DRGs identified by Medicare contractor payment safeguard projects; and

- refine Medicare regulations and guidelines to provide the best possible assurance that medical procedures are correctly coded and sufficiently documented.

The OIG itself can also contribute to training, and the Congress has specifically mandated that we do so through a program of advisory opinions. Following is a brief summary of our educational programs.

*Health Care Provider Compliance Program Guidance*

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established a national Health Care Fraud and Abuse Control Program under the joint direction of the Attorney General and the Secretary of HHS, acting through the OIG. This new program was designed to coordinate Federal, State, and local enforcement activities with respect to health care fraud and abuse. Since HIPAA's enactment, the OIG has embarked on a major initiative to promote voluntary adoption of compliance programs by provider organizations. Our goal has been to help health care providers bill the Medicare program more accurately. When they do, Medicare pays the right amount for a covered service delivered to an eligible beneficiary.

In order to encourage the adoption of compliance measures by health care providers, the OIG has worked with health care industry groups to develop model, voluntary compliance plans. They identify steps that health care providers may voluntarily take to improve adherence to Medicare rules.

The OIG guidances are very specific in identifying risk areas for a particular health care industry sector. Since enactment of HIPAA, nine health care industry sector compliance guidances have been issued, including specific ones targeted to hospitals; home health agencies; clinical laboratories; third-party medical billing companies; durable medical equipment, prosthetics, and orthotics suppliers;

hospices; Medicare+Choice organizations; nursing facilities; and individual and small group physician practices.

The OIG and the health care industry, through various organizations such as the Health Care Compliance Association (HCCA) and the Council of Ethical Organizations, have engaged in an ongoing dialogue on health care compliance to better understand and resolve the challenges associated with creating effective compliance programs. We were pleased to read in the recent HCCA annual survey of health care compliance professionals that 71 percent of health care organizations now have ongoing compliance programs in place. The General Accounting Office (GAO) has concluded that the voluntary compliance of hospitals and other Medicare providers is crucial to reducing improper payments. Hospitals reported to GAO that compliance programs foster an improved culture for "doing the right thing" and that reduction of improper payments and their attendant liabilities is a benefit that exceeds the costs of their compliance programs.

*Health Care Industry Guidance*

An important core element of the new HIPAA fraud and abuse control program is the provision of guidance to health care providers regarding potential liability for activities that may be considered fraudulent or abusive. Specifically, HIPAA requires that the OIG:

- issue upon request advisory opinions regarding the applicability of the criminal and administrative sanction provisions of the Social Security Act;

- issue special fraud alerts, upon request or otherwise, advising "the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare or Medicaid programs;" and

- issue annually a public solicitation for proposals for issuance of both new and modified existing "safe harbor" regulations regarding the applicability of the Medicare/Medicaid anti-kickback statute.

The centerpiece of the OIG's implementation of the HIPAA guidance provision has been the advisory opinion process. It is through this that parties can obtain binding legal advice as to whether their existing or proposed health care business transactions run afoul of the Medicare/Medicaid anti-kickback statute, the Civil Monetary Penalties Law, or the program exclusion provisions. Congress recently extended the authority for the "advisory opinion" process in the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. Over 60 formal advisory opinions have been issued since establishment of this function in 1997. The advisory opinion process also serves to improve the OIG's understanding of new and emerging health care business arrangements and guide the development of new safe harbor regulations, fraud alerts, and special advisory bulletins.

Since HIPAA's enactment, the OIG has promulgated nine new "safe harbors" under the Medicare/Medicaid anti-kickback statute, and clarified or modified seven existing regulatory safe harbors. These OIG issuances have all been published in the Federal Register and are also available on the OIG's web site (www.dhhs.gov/oig).

In addition, the OIG's final audit and inspection reports, as well as its annual work plan and other issuances, are published on its web site. Health care providers and other interested parties are regularly advised of new OIG issuances through a free "List Server" on its web site, which currently has approximately 9,000 registered subscribers.

## Recent Successes

The education and training programs of CMS and the OIG are paying off. Our most recent annual report on Medicare payment errors found that Medicare made $11.9 billion in improper payments in FY 2000, 6.8 percent of all Medicare fee-for-service payments. This is down substantially from the $23.2 billion, or 14 percent, first reported for 1996. Thus, 93 percent of all bills are free of error when they are submitted.

The decrease in improper payments has had a positive effect on Medicare's financial situation. from 1991 to 1996, the Congressional Budget Office (CBO) reported that Medicare's rate of inflation averaged 10.9% per year. In FY 1998, the rate of inflation for the Medicare fee-for-service program dropped to the lowest in the program's entire history (since 1965): 1.5%. Overall, CBO calculated the average Medicare inflation rate for FY 1997 to FY 2000 at 3.2%. CBO commented that: "Most of the decline can be explained by a strong effort to ensure compliance with payment rules." (The Budget and Economic Outlook: fiscal Years 2002-2011, CBO, January 2001.

This demonstrates that error reduction is possible through the concerted efforts of health care providers and Medicare administrators. But it is still too high. Billions of dollars are at stake, and years of Medicare solvency will be lost if we do not control this error rate. We believe that continued, even intensified, ongoing efforts are necessary to help further reduce improper Medicare fee-for-service payments.

I wish to digress for a moment to emphasize that there are many reasons for the improper payments covered by the annual payment error report. They range from inadvertent mistakes to outright fraud and abuse. However, our annual payment error rate audit cannot determine whether an inappropriate provider payment is the result of an innocent error, a misunderstanding of Medicare coverage, pricing, or payment rules, carelessness, mismanagement, or outright fraud. It is sometimes characterized as a "fraud error" rate. But this is incorrect. It should not be construed as such. In fact, there are no reliable estimates regarding the level of fraud in the program.

## Medicare Education and Regulatory Fairness Act of 2001

The Medicare Education and Regulatory Fairness Act of 2001 (H.R. 868) has been introduced to address some of the concerns of providers which I have discussed in my testimony. You asked the OIG to comment on this bill in our testimony, and I appreciate the opportunity to do so.

We recognize and appreciate the tremendous amount of thoughtful work that has gone into the development of this bill as well as the subsequent discussions and reviews that have been occurring since its introduction. We have also appreciated the opportunity to comment on its provisions.

Because your staff already have our detailed comments, I will limit my discussion here to the key principles underlying the bill and some of its key provisions.

*Provider Education*

First and foremost, as should be obvious from our discussion above, we strongly support increased education for health care providers. They deserve the best possible explanation of Medicare. Obviously, every attempt should be made to simplify the program so that it is easier to understand. But to the extent that complexities remain, every effort should be made to make program rules easy to understand. This will result in Medicare paying right the first time, thereby avoiding the frustrations of the overpayment collection and appeals systems.

Training can and should take on many forms--seminars, pamphlets, bulletins, dial-in question and answer services, and more formal advisory services. All these and more should be available. I have already mentioned some of the educational programs of the OIG. However, the main responsibility for provider education rests with CMS, which already provides such training and education through its intermediaries and carriers and various procedural guidances. Secretary Thompson recently announced new initiatives, including the identification of individual senior staff members to work with stakeholders, an expanded role for the Physicians' Regulatory Issues Team, more information on the Internet, and satellite broadcasts.

Thus, we support increased funding and new forums for provider training and education. We would urge the Congress, though, to make this funding available *in addition to* rather than *instead of* other administrative and program integrity functions such as claims review, as the bill now provides.

*Immunity from Investigation*

One area of concern for us is the granting of immunity from investigation under certain circumstances, such as the voluntary repayment of amounts received for erroneous claims, inquiries about Medicare policy, or participation in training programs. There is no need for such immunization. Physicians and other health care providers are not subject to civil or criminal penalties for honest mistakes, errors, or even negligence. However, those relatively few providers who would deliberately and fraudulently steal from the Medicare program would not hesitate to use this provision to immunize themselves from investigation and prosecution and, in essence, obtain interest free loans from Medicare.

*Extrapolation*

Extrapolation is the scientifically valid method of statistical sampling. It and has been fully accepted by the Federal courts as a method of estimating liability for overpayments. The bill would prohibit recoupments or offset payment amounts based on extrapolation for the first time that a provider is alleged to have received overpayments or when a provider submits a claim for advice of suitability (as provided for later in the bill in the section on education components). These provisions deprive the Medicare trust funds of the full amounts owed it and would eliminate an important tool in evaluating overpayments.

In discussing these provisions with various staff members and stakeholders, it appears to us that the objections to using extrapolation stem from two different concepts. One appears to be the idea that if a provider voluntarily acknowledges receipt of payments made in error, there need not be an obligation to repay the entire amount owed. Perhaps the thought is that erroneous bills may have been innocently submitted for some period of time before the error is discovered, and that the amount of overpayments is so high as to create a serious financial problem for the provider. Perhaps the thinking is that some recognition should be given for voluntarily owning up to the mistake or some recognition of the burden of a paying back large overpayment.

While on the surface these concepts may appear to be understandable, they do not represent sound business practice. To see this, one only need imagine what it would be like to be on the other side of this equation. If any of us were to discover that a medical insurance program had underpaid us over a period of, say, a year or two, we would probably expect to receive back the entire amount owed to us. If a telephone company overcharged a medical care provider for 12 months, the provider would probably expect credit on the whole bill, not just a recognition from the telephone company that it had made an error and will now credit only the last month. Similarly, a medical care provider might not be so understanding if Medicare had mistakenly underpaid it over a period of time.

Clearly, the correct business principle is that the amounts owed to Medicare should be fully paid, and vice-versa, providers should receive all that is due to them. However, the process whereby the amount owed is determined and the process of paying back should be reasonable and should take into account such things as cash flow needs. Thus, the proper response to this aspect of the problem is a careful examination of the overpayment collection system to ensure that it operates reasonably and efficiently. We would fully support any reasonable accommodations with regard to time frames, amounts of payment installments, methods of collection, interest rates, etc., that are needed to ensure the financial viability of providers who have received overpayments in error, while still recovering amounts owed to Medicare.

The second concern raised in connection with extrapolation is distrust of the reliability of statistical estimates. Some providers seem to believe that Medicare contractors will make assumptions that if one payment is made in error for a particular service, then all such payments are in error, and the that the contractor will demand full repayment of all such payments made. Alternatively, some providers may believe that samples used are too small to use for reliable projections. We have found that Medicare contractors do use probe samples as an initial estimate of repayment amounts, but they also offer the provider the option of a statistically valid random sample to develop a reliable estimate. Such sampling reduces burdens on providers considerably when compared to making a thorough claim-by-claim review, which is usually impractical and extremely burdensome to providers. Thus, the use of extrapolation is a way of minimizing, not increasing, provider burdens. It is also an essential tool for Medicare to recover the amounts owed to it.

*Other Concerns and Opportunities*

Immunity and extrapolation are not the only concerns we have about the bill as currently drafted. Others pertain to the length of time allowed for repayment, availability of documentation, and the like. At the same time, the resolution of the issues surrounding immunity and extrapolation as discussed above reflects what we believe is a promising approach to resolving concerns about burdens

on providers. We believe that most of these concerns can be addressed through a thoughtful examination of the overpayment collection process, with adjustments as necessary to provide reasonable procedures to secure for Medicare the amount due to it, while at the same time respecting the practical needs of providers who are doing their best to comply with Medicare rules. We will continue to work with your staff and stakeholders to accomplish this.

## Fear of Prosecution

Providers' concerns follow two general lines of thought. The first is about burdens and complexity, a sense that things are too complicated, too hard to understand, and that paperwork requirements are excessive. I hope that many of the ideas discussed in this testimony will be helpful in alleviating these concerns.

At the same time, there seems to be a general concern that providers, however honest and responsible they may be, will be subject to audit or criminal prosecution just because they make mistakes. Some of the provisions of the proposed Medicare Education and Regulatory Fairness Act of 2001 are intended to address this aspect of provider concerns--by providing some degree of statutory protection from unreasonable audit, investigation, prosecution, and penalties. I thought it would be worthwhile to end my testimony with a brief discussion of this issue.

The Office of Inspector General has repeatedly stated its conviction that the great majority of health care providers are honest and committed to providing high quality medical care to Medicare beneficiaries. They need not fear unjust prosecution. Under the law, providers are not subject to civil, administrative, or criminal penalties for innocent errors, or even negligence. The government's primary enforcement tool, the Civil False Claims Act, covers only offenses that are committed with actual knowledge of the falsity of the claim, reckless disregard or deliberate ignorance of the truth or falsity of a claim. The False Claims Act does not cover mistakes, errors, or negligence. The OIG is very mindful of the difference between innocent errors ("erroneous claims") and reckless or intentional conduct ("fraudulent claims").

Rumors of unjustified arrests, investigations, and audits; non-specific allegations about excessive enforcement actions; and sweeping characterizations of the motives and attitudes of oversight professionals are simply not warranted by the record. Such statements themselves contribute to rather than alleviate the concerns of health care providers. The solution is to improve understanding of the oversight functions and to increase, through communication, the mutual trust and respect of the medical care and program integrity professions. This is far better than further increasing the complexity of the Medicare program through additional unnecessary laws and regulations. I hope my statement here will contribute to that result.

## Conclusion

Our Medicare provider community is important to all of us. I hope that the suggestions provided here from the Office of Inspector General will be useful in protecting the financial integrity of the program, reducing frustrations of providers and administrators alike, and making the program better for Medicare beneficiaries. We are ready to help this committee and all parties involved to find a better way to manage this program. Thank you for the opportunity to present these ideas to you.