



August 24, 2007

Herb Kuhn, Acting Deputy Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1385-P  
P.O. Box 8018, Baltimore, MD 21244-8108  
By electronic submission

*Re: Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Proposed Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Proposed Elimination of the E-Prescribing Exemption for Computer-Generated Facsimile*

Dear Mr. Kuhn:

Thank you for the opportunity to comment on the proposed rule regarding revisions to the payment policies under the Physician Fee Schedule, and other Part B Payment Policies for CY 2008, document, CMS-1385-P. The American Medical Group Association (AMGA) is an association that represents medical groups, including some of the nation's largest, most prestigious multi-specialty medical practices, independent practice associations and integrated health care delivery systems. AMGA members' 65,000 physicians deliver health care to more than 50 million patients in 40 states, including 15 million capitated lives.

#### **CODING--ADDITIONAL CODES FROM 5-YEAR REVIEW**

***AMGA Recommendation: AMGA strongly urges CMS to wait for and fully consider the RUC's decisions about the work and practice expense for CPT 93325 before taking any action on the proposal to bundle this code into others.***

CMS proposes bundling CPT 93325, Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography), into CPT codes 76825-8, 993303-4, 993308, 993312, 993314-15, 993317, 93321, and 93350. This is of tremendous concern to our members who are cardiologists and represents a substantial and unwarranted cut for cardiology services payments.

We have learned that our colleagues at the American College of Cardiology (ACC) have been working with CMS to resolve concerns about 93325 for nearly two years. CMS identified 93325 as a procedure to be included in the most recent five year review of the RBRVS. The ACC conducted a survey and presented a recommendation on the physician work RVUs to the AMA/Specialty Society RVS Update Committee (RUC). The RUC did not address the work RVUs, but instead recommended that the issue be

referred to the CPT Editorial Panel to consider whether 93325 should be bundled with CPT 93307 (transthoracic echocardiography). The ACC and the American Society of Echocardiography (ASE) disagreed with this recommendation because 93325 is used with many codes other than 93307 and therefore, they did not propose a new code combining 93307 and 93325 at the time.

In March, 2007 ACC and ASE submitted a proposal to the CPT Editorial Panel for a new code combining 93307, 93325 and 93320 (spectral Doppler). The CPT Panel approved the new code in June for implementation in January 2009. The ACC proposal and the CPT Panel decision left 93325 available for use as an add-on code for all echocardiography base codes other than 93307. The ACC and ASE are now conducting a survey to determine the physician work and practice expense associated with the new code, and will present a recommendation to the RUC in September. This new code is fully expected to address any outstanding issues relative to Medicare utilization of 93307 and will have been analyzed in depth by appropriate national medical societies, the CPT editorial panel, and the RUC.

In the current Notice of Proposed Rulemaking for the 2008 Medicare Physician Fee Schedule (CMS 1385-P), CMS proposes to bundle 93325 into all other echocardiography procedures. Payment rates for the other echo procedures would not be adjusted to reflect the physician work and practice expense associated with 93325. CMS asserts that 93325 is now an integral part of all echocardiography procedures. We want to make certain that CMS staff is aware of the new code approved by the CPT Editorial Panel and to note that the vast majority of Medicare billing for 93325 occurs in conjunction with 93307, so separate reporting of 93307 will fall dramatically when the new code is introduced.

Color flow Doppler is not intrinsic to all echocardiography procedures. Use of the color flow add-on varies significantly across the different echo services. There is considerable diagnostic value in use of this technology and there is distinct physician work and practice expense associated with 93325 that is not accounted for in the relative value units for the other echo codes. Bundling, as proposed, flies in the face of these realities and is, without additional payment, inappropriate and unfair.

The public-private partnership of RUC and CMS has been successful for a long time and produces thoughtful decisions and outcomes. We urge CMS to continue in its cooperative efforts in that regard. Finally, we concur with the ACC and strongly urge CMS to wait for and fully consider the RUC's decisions about the work and practice expense for the new code before taking any action on CPT code 93325.

## **PROPOSED ELIMINATION OF EXEMPTION FOR COMPUTER-GENERATED FACSIMILES**

***AMGA Recommendation:*** *AMGA strongly recommends that CMS provide an additional two years to properly educate all parties involved in e-prescribing to allow time for software upgrades, and in some cases, software purchase and testing, to take place.*

AMGA supports the evolutionary adoption of SCRIPT-enabled software and the use of e-prescribing. There are obvious benefits to moving in this direction. Among them are increased patient safety; cost savings, once systems have been paid for and established; and efficiency. However, based on information we have received from our members, we strongly suggest allowing an additional two years before dropping the exemption.

In response to CMS' request for information concerning industry readiness, one of our members, the Everett Clinic, Everett, Washington, a 225 physician group practice, conducted an informal survey of pharmacies in its region (independent pharmacies, chain retailers and mail order pharmacies). Everett Clinic found that less than half of the pharmacies were aware of the CMS proposal to end the computer generated fax exemption (see attached letter from the Everett Clinic). Of the 47% of pharmacies currently accepting electronic prescriptions, 98% receives 1% or less of its total prescriptions electronically. When asked about barriers currently preventing implementation of e-prescribing, costs associated with implementation and computer system limitations, were cited by the pharmacies.

Presently, 95% of the pharmacies surveyed are printing electronic prescriptions and manually reentering the information prior to dispensing. The benefits of e-prescribing are obviously not being realized when prescription information is being manually reentered. Moreover, it has also come to our attention that not all software vendors, even those offering e-prescribing programs, have products that are compliant with the SCRIPT standards. Hence, the barriers to acquiring compliant software for some already invested in electronic infrastructure, are elevated.

Although these results are informal, they clearly indicate that many pharmacies are not prepared to deal with the elimination of the facsimile exemption. Until all trading partners are ready to implement SCRIPT-enabled software, the elimination of the computer generated fax exemption makes little sense, given CMS' stated objectives.

Regardless of CMS' decision, several important considerations need to be incorporated into a final rule. Under no circumstances should inability to communicate via required means become a burden to patients. Those seeking to have a prescription filled should not be denied services nor in any other way be penalized because a pharmacy and/or prescriber is not compliant, hence pharmacies must be able to accept faxed prescriptions even if the pharmacy cannot be sure that the prescriber transmitted the prescription in compliance with the regulation (i.e. the prescriber transmitted the fax by a fax machine). Provisions must exist to cover circumstances when either side of a prescription filling communication cannot accept electronic transactions. Faxed prescriptions must be allowed as a back-up option when e-prescribing systems are temporarily not functional.

If implemented as proposed, elimination of the exemption will likely produce more use hand written prescriptions rather than greater participation in SCRIPT compliant e-prescribing. AMGA believes that CMS should provide another two years to educate properly all parties involved in these transactions and allow time for software upgrades.

and in some cases, software purchase and testing, to take place. We therefore strongly urge CMS to postpone finalizing this proposal until January of 2010.

### **TRHCA--SECTION 101(b): PQRI**

***AMGA Recommendation:*** *AMGA requests that CMS allow medical groups to collect and periodically submit statistically valid, medical group level quality data focusing on the quality measures for high cost/high volume chronic conditions such as those included in the Physician Group Practice demonstration; and allow payment and measurement at the group level.*

In December 2006, Congress passed the Tax Relief and Health Care Act of 2006 (TRHCA) which created the Physician Quality Reporting Initiative (PQRI). Under the PQRI, physicians may receive a 1.5% bonus payment from CMS if they submit data on various quality indicators.

The PQRI is designed to accept data from solo physicians and small group practices. Because of administrative and technology issues, most large multi-specialty medical groups are unlikely to report data under PQRI. Costs to submit data using the G-code system are prohibitively expensive since retooling existing, sophisticated, often proprietary software, and training personnel, are expensive and onerous. Estimates at creating interfaces necessary for medical group Electronic Medical Records (EMR) systems to abstract and submit data through G-codes range in the hundreds of thousands of dollars.

In response, multi-specialty medical groups developed a reporting proposal (Proposal) that would encourage medical group participation in the PQRI. The Proposal allows groups with the capability to collect and distribute quality data to submit data through the existing Medicare Physician Group Practice (PGP) Demonstration process or through existing data registries. Quality measures would focus on high cost/high volume conditions included in the PGP demonstration. In fact the quality measures in the PGP demonstration cover the majority of costs paid by Medicare. Patients with a diagnosis of Congestive Heart Failure alone make up approximately 43% of total Medicare payments.

Because the PGP quality indicator set includes process and outcomes measures, providers would be rewarded for results, not just reporting, representing a significant step in transforming Medicare into a better purchaser of health care. Moreover, the Proposal would support the use of electronic medical record systems to report quality data that will provide more reliable and actionable data for improving beneficiary care.

Many medical groups are large enough for sampling to provide sufficiently robust data to measure quality. They also have a proven track record as efficient providers of care. By and large, such medical groups perform as a single entity, should be measured as a single entity, and have any bonuses or rewards paid as a single entity, allowing use of their existing mechanisms to efficiently distribute feedback reports and funds.

We ask CMS to allow medical groups to collect and periodically submit statistically valid, medical group level quality data; focus quality measures on high cost/high volume chronic conditions such as those included in the Physician Group Practice demonstration; and allow payment and measurement at the group level. These steps would produce large amounts of reliable data focused on high cost diseases and would advance the quality of care.

To that end, we follow with an outline of key elements, with some observations and commentary, that would support this proposal and would allow all those with capability and interest to report quality and related data using periodic, aggregated reporting based on data sampling from existing electronic sources (supplemented as necessary by manual abstraction and similar means):

## Medical Group-Level Reporting Proposal for PQRI

### 1. Medical group-level reporting option for PQRI

- 1.1. For physicians who are members of a medical group that elects the medical group option, the medical group would become its own reporting entity
- 1.2. Patients would be assigned to medical groups as in the PGP demonstration project, based on the plurality of primary care services (retrospective, based on claims data)
- 1.3. Measures to be reported:
  - a. Initially, the 32 measures defined in the PGP demonstration project, phased in over three years (year 1: diabetes; year 2: congestive heart failure, coronary artery disease; year 3: hypertension, screening for breast cancer and colorectal cancer)
  - b. Future goals: Broaden disease coverage (COPD and others), receive payment for outcomes, and expand measures to include patient-reported outcomes

### 2. PQRI mechanisms for quality reporting—three options:

- 2.1. Current PQRI method: Claims-based reporting via G codes and CPT II codes
- 2.2. Practical immediate approach: Extend the quality component of the PGP demonstration
  - a. Advantages
    - Establishes the concept of medical group-level reporting, and extends the option to all medical groups capable of reporting
    - Accepted mechanism and measure set for reporting at the medical group level
    - Machinery is already in place, via RTI and the Iowa QIO (IFMC)
    - Does not require an EMR or registry (internal or external), but these tools can make medical record abstracting more efficient
    - Practical way for medical groups to take a pro-active position on accountability for quality and care coordination
    - Could substantially increase participation in PQRI, in the short term
  - b. Disadvantages
    - Fundamentally claims-based, so this could delay CMS's registry-based reporting

- Requires substantial effort for medical record abstraction (~ 1.0 FTE per medical group for the current five modules in year 3, with the current sampling method)
- Data collection is retrospective (may require locating charts from 2 years ago)
- Long delays in obtaining feedback; comparative data is limited to other PGP demo participants—no opportunity to stimulate rapid-cycle improvements in care

2.3. Future approach: Registry-based reporting, from EMR and claims data

a. Advantages

- Greater accuracy—determine denominators from EMR problem list or disease registry within medical group, eliminating the false positives (6–15%) and false negatives (25%) that occur in claims data<sup>1</sup>
- Reflects entire population of patients treated—does not require sampling
- Physicians have more time to focus on the patient—no additional documentation required, enhancing their productivity
- Registry would provide timely feedback and comparative performance data, at multiple levels—medical group, practice site, specialty
- Provides incentives to invest in EMRs and systems and services that enhance care coordination, rather than billing systems
- Automatically tied to structured documentation in EMR—does not require audit of individual medical records, only of the overall process

b. Challenges

- Requires disease registry or structured problem lists in EMR, coded so they can be mapped to accepted measure definitions, most of which are based on claims data (e.g., map SNOMED-coded problems in EMR to ICD-9-CM Dx codes)
- Requires specific prompts in EMR to create structured data (vs. dictated notes)
- Medical group must document in the EMR those services that were obtained from other providers (often diabetic eye exams, mammograms, flu vaccine; may include HbA1c testing for diabetes patients followed by an outside endocrinologist)
- Patient attribution—in the PGP demo, “assigned beneficiaries are those for whom the PGP has provided more primary care services than any other provider” (retro-spectively attributed, based on Medicare claims from all providers)

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<sup>1</sup> Using claims data to define patient populations can introduce significant errors. In AMGA’s work with Health Hero Network on a CMS demonstration project involving home monitoring and care management for high-cost Medicare beneficiaries, claims data are used to identify patients who have CHF, COPD, or diabetes. According to an independent review of medical records by Milliman, 10–16% of patients identified by claims data as having CHF or COPD, even using stringent criteria, did not actually have the disease. The corresponding figure was 5–6% for diabetes.

Participants in the Medicare Physician Group Practice Demonstration have reported similar error rates when using claims data to populate disease registries. Depending on definitions and timeframes, some or all of these “false positive” patients would be included as denominator cases when quality measures are based on claims data.

Relying on claims data can also lead to many “false negatives.” A recent study performed for CMS by the Palo Alto Medical Foundation and the California QIO found that only 75% of patients who had diabetes were identified as such, using standard definitions based on administrative data. As a result, many diabetes patients are omitted from quality measures based on claims data.

### 3. Other issues

- 3.1. Payment mechanism—three options:
  - a. Replicate both efficiency and quality components of PGP demo
  - b. Extend quality component of the PGP demo—omit weighting system?
    - In the PGP demo, claims-based measures are weighted 4, abstracted measures 1
  - c. Mirror pay-for-reporting concept in the current PQRI program
- 3.2. Current CMS exploration of registry-based reporting (addressed in the NPRM for updating the Medicare fee schedule)
  - a. This may create another option for medical groups with EMRs and a registry like Anceta or WCHQ that could support the PGP measures or their functional equivalent
  - b. CMS essentially proposes registry reporting at the physician level, with 74+ measures, rather than the medical group level, with a more focused set of measures. The current thinking on use of registries and the five options mentioned in the proposed rule, all share the fundamental focus that is merely variation on the theme of G code and individual physician reporting, a fatal flaw from the perspective of AMGA
- 3.3. Additional costs
  - a. For the PGP demo, CMS contracts with RTI and IFMC (Iowa QIO), and medical groups incur costs for medical record abstraction and data management
  - b. With registry reporting, providers would presumably pay costs of registry, and CMS would benefit from “consolidation” (dealing with a small number of systems that meet their specs, as for HospitalCompare; same as for Joint Commission Core Measures)
- 3.4. Sampling—three uses for a more efficient (adaptive) method:
  - a. For medical record abstraction in the proposed medical group reporting option for PQRI (incorporate adaptive sampling method into data collection tool provided by IFMC and pre-populated with claims data by RTI, or into registry like Anceta or WCHQ)
  - b. For auditing medical record abstraction in the proposed expansion of the PGP demo
  - c. For medical record abstraction that may be required in CMS’s proposal for registry-based reporting (may include a full set of 74+ measures)

### 4. Basic Quality Reporting Mechanism in Current PGP Demonstration Project

- 4.1. RTI extracts data from Medicare National Claims History (NCH) File (approx. 6 months lag)
- 4.2. Assigns beneficiaries to medical group providing the plurality of primary care services during the year (retrospective)
- 4.3. Selects patient population for each disease “module,” based on claims data
  - a. Diagnosis codes, services provided
  - b. Limited to the assigned beneficiaries with full-year Medicare eligibility and at least two office or other outpatient E&M visits at the PGP
- 4.4. Computes performance on claims-based measures (including claims from other providers)
  - a. Topping-up option (100% of patient population): medical groups may request list of numerator cases lacking evidence of compliance in claims data, and may report compliance from medical record or on-line system that is available at the point of care
  - b. Hybrid option (sample of 411 patients, plus 50% oversample): medical group may choose to abstract data for claims-based measures, in which case RTI will pre-populate the abstraction tool with data from claims
- 4.5. Creates random sample of patients for medical record abstraction (for non claims-based measures and hybrid option for claims-based measures) and pre-populates data collection tool developed by IFMC with patient demographics and other information from claims

- a. 411 patients per module, plus 50% oversample (total 615 patients)
  - b. Same sample for all measures within a module (except primary prevention), although different patients may be eligible for individual measures
  - c. If fewer than 411 patients qualify for a measure (e.g., atrial fibrillation), the entire patient population is used
- 4.6. Medical group abstracts data for sample patients, using the data collection tool, and uploads data via QNet
- 4.7. RTI provides feedback reports to the medical group—currently in performance year 3 of PGP demo, but groups have not yet received all reports from performance year 1
- 4.8. Calculate quality component of performance payment
- a. Claims-based measures are weighted 4 times abstracted measures
  - b. Reward both quality improvement and high quality—earn quality-based payments if, for each separate measure, the medical group:
    - Achieves the higher of 75% compliance or the Medicare HEDIS mean **OR**
    - Demonstrates 10% reduction in the gap between their administrative baseline and 100% compliance **or** achieves the 70<sup>th</sup> percentile of the Medicare HEDIS level

AMGA supports development of structural measures to be used as part of the PQRI program. Broadening reporting beyond a focus on single medical specialty/disease specific guidelines and measures will aid evolution to strategies that encourage the provision of coordinated care that emphasizes the necessary interdependency of primary care and specialty care.

The use of several kinds of measures that are most likely to be indicators of patient-centered care is warranted. These indicators include: Electronic Medical Record systems; electronic patient registries; professional care coordinator(s), the use of structured or planned visits; multi-disciplinary case management; care coordination mechanisms, such as timely notification to all practitioners regarding a change in treatment or prescriptions; written feedback between primary care and specialists regarding urgent referral visits; and, creation and maintenance of treatment plans based on individual patient needs rather than disease-specific treatment guidelines.

AMGA supports development of structural measures for use in the PQRI but recommends specifically creation and payment of incentives for those who meet these performance measures:

Structural Measures: EMR systems, electronic patient registries, home or telephonic monitoring devices, professional care coordinator(s), integrated teams of primary and specialty care.

Process Measures: Patient monitoring, case management, medication management, written (electronic or paper) feedback between primary and specialty physicians regarding treatment changes and referrals, multi-specialty treatment plans, patient self-management training.

Outcomes Measures: Reduced hospitalizations, re-admissions, and bed days of care (BDOC); reduced nursing home admissions, re-admissions and BDOC; reduction in ER visits; patient satisfaction surveys; and savings compared to Medicare fee for service baseline.

## **IDTF ISSUES**

***AMGA Recommendation: AMGA suggests targeted oversight of non-compliant IDTFs, including audits, monitoring, and enforcement to address existing compliance problems and does not oppose the intent of the performance standards.***

In our comments for the CY 2007 final rule regarding Independent Diagnostic Testing Facilities (IDTF) regulations, we supported CMS' stance vis a vis IDTFs, even calling for a fundamental reexamination of the need for such entities. While CMS construed our comments as a call for abolition of IDTFs, we meant only to suggest a reexamination of the IDTFs that engaged in impermissible acts. No IDTF should be closed that is compliant with law and regulation and meets the service needs of otherwise un-served communities and patients.

CMS' approach to solving long standing concerns and demonstrated compliance problems continues to emphasize application of additional layers of performance standards. We remain unconvinced that more ineffective actions along the lines of those taken in the past, will yield compliance remediation results. We believe that the answer to problems in this quarter lies in audits, monitoring and enforcement actions where warranted. However skeptical we may be about "more of same," we do not oppose the intent of performance requirements CMS posits.

## **PHYSICIAN SELF-REFERRAL PROVISIONS**

***AMGA Recommendation: We urge CMS to reconsider and rescind the proposed changes to per-click arrangements and to study their scope and effects carefully to determine if concerns for fraud and abuse exist, and what the impact on patient care would be if such arrangements were significantly modified.***

The proposed solution to addressing problems that seem to have begun with anatomic pathology "pod" labs, and perhaps other professional diagnostic work, will compound already complicated and burdensome regulations, and may produce significant unintended consequences. At the risk of stating the known, we point out that our medical care financing system is unique. At the Federal level, it is a heavily regulated system that imposes price fixing, among many other rules, on a significant sector of the realm, by some estimates 40 percent of total health care spending. This so-called pluralistic delivery system also provides a large role for the private sector, regulated, by and large, by the States, which imposes its own volume control, payment, and other limitations and rules. However, market forces play a part, albeit in limited form, in this.

Most physicians are, even if they tend not to think of themselves in this vein, are self-employed, small business people. The ability to generate a profit is fundamental to the existence of this approach to health care financing. The proposed rules regarding

physician self-referral provisions call into question some of the basic assumptions built into the system. The professional component of Medicare billing is priced via a long standing, scientific approach that takes numerous inputs into account and arrives at a Medicare reimbursement rate. Other Federal programs use some or all of these formulations for their payment bases and, on a selective basis, many private payors follow suit.

This price fixing confronts the buying, selling and other market forces that remain in the mix and produces tension: A scientific, input based, regionally, and otherwise adjusted fee, is supposed to be the correct payment for a service. The creative, entrepreneurial, efficiency-seeking steps taken by buying and selling entities, applying their market leverage, sometimes produce arrangements that call into question the correctness of the Federally arrived at price. This dynamic is an integral feature of the system. The changes being proposed in the notice of proposed rulemaking challenge this fundamental reality, an underpinning of the pluralistic system: Either Medicare fees are correct or they are not. If not, the whole longstanding RBRVS system is challenged. That is neither desirable nor necessary.

On the matter of “services under arrangement” we point out that a comprehensive look at such arrangements is needed to gain deep understanding and draw proper conclusions about this matter and about MedPAC’s suggestions. Reliance on concerns and anecdotal evidence is not sufficient to that end. We know from some of our members that there are services done under arrangements that do not result in higher utilization and referral abuse. Many of the arrangements are leases or other under arrangements contracts, do result in significant community and patient benefit and avoid duplication of services, thus producing costs savings to the program overall. Such favorable circumstances should be identified and must factor into any regulatory changes contemplated.

We believe that the appropriate amount of regulation to assume program integrity is warranted, but no more than that should be applied. CMS has seeming viewed its role from an almost prosecutorial perspective, casting a broad net with presumed wrongdoing as the focal point for putative preventive action. Rather than auditing and investigating real or potential abusive and impermissible practices, and taking appropriate administrative or legal action, the agency is using the proverbial “cannon to swat the ‘pod’ lab fly”. We strongly suggest a full reexamination of the problem and application of narrowly drawn remedies.

We ask CMS to consider these kinds of actions rather than risk adding unnecessary complexity, hence confusion and heightened risk of unforeseen, negative repercussions on the broader and non-fraud and abuse problematic practice of medicine:

- Seek from the HHS Office of Inspector General issuance of a special fraud alert directed to the practice of anatomic pathology and “pod” lab practices
- Strengthen interpretation to maximize the enforcement utility of Civil Money Penalties and Exclusion for Circumvention Schemes, 42 USC 1395 nn (g) (4)<sup>2</sup>
- Employ tools already available to investigate abuses and take remedial action where warranted

We are frankly confused at the stance CMS proposed *vis a vis* the unit of service payments in space and equipment leases (per click arrangements). CMS ruminates on the long history of actions and contemplations on the subject of per click arrangement and related issues. The rationale for allowing such arrangements was detailed. The abnegation of this history was succinct and almost nonchalant, effectively prohibiting legal and allowable arrangements in spite of the fact, as stated in the proposed rule, that “...the statute does not expressly forbid per-click payments to a lessor for patient referred to the lessee.”

We question CMS’ premise that wholesale change is necessary based only on the speculation of wrongdoing. There seems to be neither evidence of wrongdoing cited nor a suggestion that there is wrongdoing, only that the stage may be set for it. There are countless per-click arrangements in place (they have been allowed for years), likely representing millions of dollars of joint venture enterprises, equipment acquisition costs, service agreements, etc., that would need to be disassembled, and in a hurry. Many of such deals involve deployment of high cost equipment such as MRIs or stereotactic radiosurgery (such as the GammaKnife<sup>®</sup> or CyberKnife<sup>®</sup>) technology that serves patients, sometimes in very large service areas. If these arrangements must be dismantled, there is a heightened risk that access to the machinery may be lost. The implications for disruption of patient care and normal business arrangements are huge. We urge CMS to reconsider and rescind this proposed change and to study per-click arrangements, their scope and effects to determine if susceptibility concerns for fraud and abuse do, in fact, exist, and if so, what the impact on patient care would be if such undertakings were significantly modified or disappeared altogether.

The in-office ancillary services rule exception was created to facilitate and allow continuation of patient care as widely practiced in the United States. Patients had available a number of diagnostic testing capabilities that the doctor could use in the

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<sup>2</sup> (4) Civil money penalty and exclusion for circumvention schemes

Any physician or other entity that enters into an arrangement or scheme (such as a cross-referral arrangement) which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil money penalty of not more than \$100,000 for each such arrangement or scheme. The provisions of section 1320a-7a of this title (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

practice setting to provide and enhance patient care in terms of convenience for the patient and proximity to the physician for diagnostic and treatment application. While the medical practice world has changed a great deal since this exception was implemented, the underlying realities of patient care and convenience have not. We believe that no changes to the exception should be considered without great study and analysis. If problems are unearthed, solutions should be focused and targeted to the practices in question. The principles and specifics of the in-office ancillary services exception, as currently manifested, should stand.

Thank you for the opportunity to comment. Should you have questions or desire additional information, please contact George Roman, Senior Director, Health Policy, of my staff at (703) 838-0033 ext. 342 or by email at [groman@amga.org](mailto:groman@amga.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Donald S. Fisher".

Donald S. Fisher, Ph.D., CAE  
President and CEO

Attachment: Letter from The Everett Clinic

# The Everett Clinic

For the whole you.

George Roman  
Senior Director, Health Policy  
American Medical Group Association  
1422 Duke Street  
Alexandria, VA 22314

July 26, 2007

Subject: CMS Proposed Rule Change: E-Prescribing and Computer Generated Fax Exception

Dear Mr. Roman:

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule on June 29, 2007 that included a provision that would eliminate the exemption for computer generated faxes from the e-prescribing standards effective January 1, 2008.

At the Everett Clinic we began implementing electronic prescribing in 2003. All of our providers have sent some prescriptions electronically. Currently, we electronically send over 20,000 prescriptions weekly. We will have the SCRIPT standard implemented as of 10/1/2007 via the Epic Ambulatory system. However, we will be using a computer generated fax to transmit prescriptions. Greater than 95% of Epic practices are planning on doing this as of 1/1/2008.

We will not be able to accomplish a timeline of implementation by 1/1/08. This is true for many medical groups and we believe a timeline of 1/1/2010 is more reasonable and attainable. Being able to utilize fax machines as the transmission device after 1/1/08 ensures the continued implementation of Electronic Health Records and a continued advancement in patient safety.

We have completed a survey of 160 pharmacies which includes major regional and national chains, mail order and independent pharmacies. They do prefer receiving electronically generated faxed prescriptions vs. hand written prescriptions. Their awareness of the rule changes and readiness are as follows:

- 47% are aware of the CMS Rule change
- 78% can accept an electronic prescription into their pharmacy computer system
- 47% are currently accepting electronic prescriptions with 98% receiving 1% or less of their total prescriptions electronically
- Cost/transaction and the computer system limitations are the two reasons noted why pharmacies are not implementing the electronic receipt

Advanced Imaging  
Allergy  
Anesthesiology  
Behavioral Health  
Cancer/Oncology  
Cardiology  
Cosmetic Surgery  
Critical Care  
Dermatology  
Diabetes/  
Endocrinology  
Ear, Nose & Throat  
Facial Rejuvenation  
Family Practice  
Gastroenterology  
Geriatric Care  
Gynecology  
Hand Center  
Head & Neck  
Surgery  
Hearing Aid Center  
Hematology  
Infectious Disease  
Internal Medicine  
Laboratory Services  
Neurology  
Obstetrics  
Occupational  
Medicine  
Ophthalmology  
Orthopedics  
Outpatient Surgery  
Centers  
Pediatric/  
Adolescent Care  
Pharmacy Services  
Physical Medicine  
& Rehab  
Pulmonary  
Rheumatology  
& Arthritis  
Skin Surgery  
& Laser  
Sleep Center  
Spine Center  
Sports Medicine  
Surgery  
Urology  
Vision Centers  
Walk-In Clinics

3901 Hoyt Avenue  
Everett, WA 98201  
425-259-0966  
www.everettclinic.com

- 95% are printing their prescriptions out and reentering their prescriptions after receiving them electronically due to computer systems limitations

Moving back to paper prescriptions decreases the quality of patient care in the following ways

- No integration of prescribing data into Electronic Health Records
- Reintroduction of medication errors that are part of written prescriptions and are eliminated via electronic prescribing and fax transmission (eg: bad handwriting, missing information)

We believe in moving to electronic prescribing utilizing the SCRIPT standard. However, we would like to ensure the timeline is able to be implemented. We believe a more reasonable date for full electronic implementation is 1/1/2010.

Sincerely,



Al Fisk, MD, MMM  
Medical Director  
The Everett Clinic



Jennifer Wilson Norton, RPh, MBA  
Director of Pharmacy Services  
The Everett Clinic