

EHR REPORT

Meaningful Use Criteria: What's Missing

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Since the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act in February of 2009, there has been a tremendous amount of discussion about the idea of “meaningful use.” Associated with the meaningful use criteria are financial incentives for those who adopt an electronic health record and care for Medicare and Medicaid patients. Such incentives may total more than \$40k-60k per provider. Those who fail to meet the criteria will find their reimbursements reduced beginning in 2016.

Despite the abundance of commentary and speculation over meaningful use, until recently the term had not actually been defined. And now that the full set of rules for meaningful use is available, it might surprise some to know what has actually been excluded from the criteria.

In explaining the meaningful use concept at the beginning of this year, the Department of Health and Human Services laid out a number of objectives and priorities centered on improving the quality, safety, efficiency, and accessibility of care. Any aspects of electronic health record (EHR) implementation that do not meet those goals have been specifically left out of the criteria. In doing so, the intent is to challenge health care providers to move forward toward the goal of EHR implementation, while acknowledging the limitations of the technology currently available.

The first and most fascinating exclusion is any requirement for encounter note generation. The criteria specifically state that it will not be necessary for providers to document their encounter notes using the EHR, commenting that proper documentation is “a medical-legal requirement and a component of basic EHR functionality, [but] is not directly related to advanced processes of care or improvements in quality, safety, or efficiency,” according to the report (Federal Register 2010;75:1843-2010).

In other words, while most EHR products emphasize electronic note generation, the authors feel this does not provide a significant benefit over handwritten charting in meeting the goals of HITECH.

Many might disagree with this statement, but others may be breathing a sigh of relief. The challenge of typing office notes has long been among the most feared by physicians with limited computer skills. These providers may rest assured, knowing that—for now—holding onto pen and paper for documenting patient encounters will not preclude them from the financial incentives under the HITECH act. Still, it might be difficult to implement an EHR without this piece, as once an office becomes dependent on the technology, workflow can be significantly hindered by searching for documentation that is not in the electronic record.

To address this, some practices have chosen to scan in handwritten notes. Unfortunately, this might preclude critical data points from being captured by the system, and make it impossible to meet some of the quality reporting goals laid out elsewhere in HITECH.

A second intentional omission in the criteria is the requirement that providers make educational resources available to

patients. In spite of a clear objective to involve patients more in their care, the authors are reluctant to make this a necessity. They admit that proper information and education are “a critical component of patient engagement and empowerment,” but acknowledge that “there is currently a paucity of knowledge resources that are integrated within EHRs, that are widely available, and

that meet [our] criteria, particularly in multiple languages.”

As it turns out, many EHR products do include patient education resources, but these often are limited in quality and come at an additional fee. As an alternative, online resources available through Web sites such as familydoctor.org and emedicine.com provide educational tools that are free and peer reviewed.

For adult patients with type 2 diabetes in addition to diet and exercise

Onglyza™ Partnering to improve glycemic control.

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- Onglyza is widely accessible,¹ with most commercially-insured eligible patients paying only \$10 per month[†]

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ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

ONGLYZA should not be used for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.

ONGLYZA has not been studied in combination with insulin.

*Pioglitazone or rosiglitazone

[†]Based on Tier 2 coverage and the Onglyza Value Card Program.

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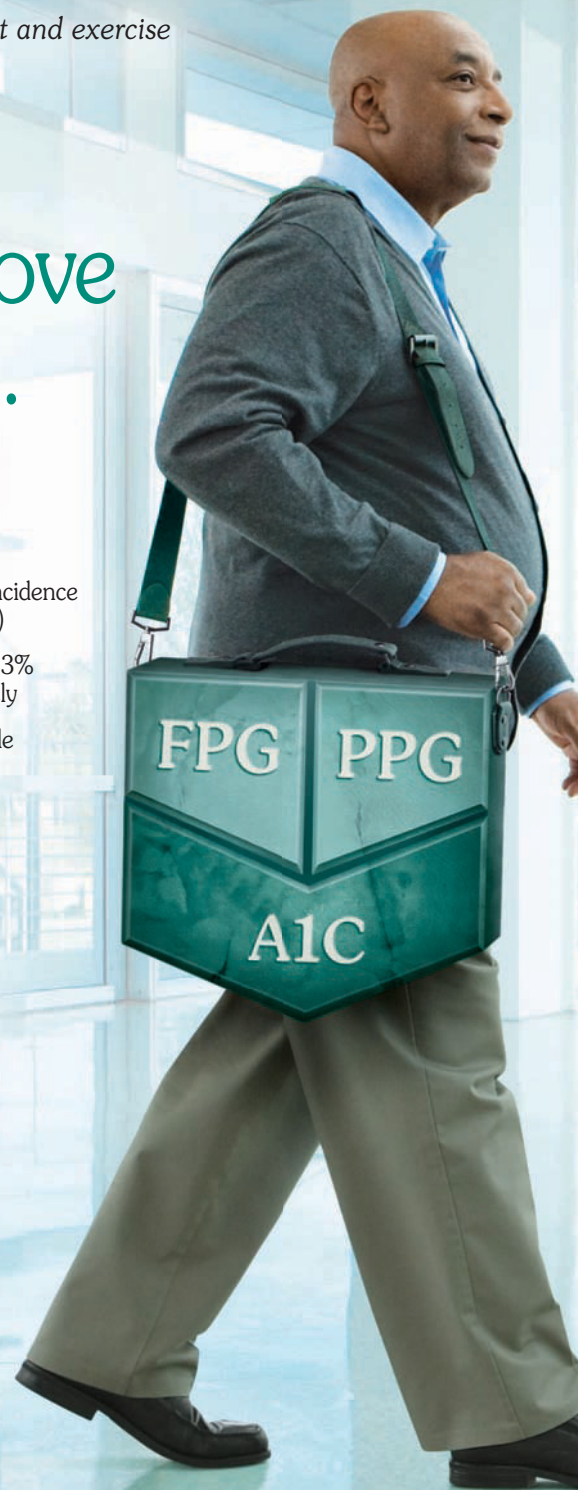
Reference: 1. Fingertip Formulary® data as of April 9, 2010. Data on File, April 2010.

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Another anticipated requirement that's been excluded from the criteria is the necessity for orders to be transmitted electronically from care provider to testing, diagnostic imaging, or treatment facilities. It should be noted that computerized physician order entry (CPOE) is greatly emphasized under HITECH, with the objective that 80% of orders be entered through the EHR. CPOE is defined as "the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and

other auxiliary services) from a computer or mobile device." But in the criteria released so far, the requirements "will not include the electronic transmittal of [those orders] to the pharmacy, laboratory, or diagnostic imaging center." Since the guidelines do require e-prescribing to meet criteria, further clarification is needed to determine which orders must be sent electronically and which do not.

A review of these exclusions makes it apparent that no one is completely sure how the meaningful use criteria will affect day-to-day practice. The authors of

the legislation have attempted to challenge the status-quo and yet maintain a practical perspective on what is possible with the resources at hand. Many physicians will remain skeptical of any government intervention in health care but can at least now be assured that the financial incentives are attached to a fairly practical set of requirements. ■

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Important Safety Information

- **Use with Medications Known to Cause Hypoglycemia:** Insulin secretagogues, such as sulfonylureas, cause hypoglycemia. Therefore, a lower dose of the insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with ONGLYZA
- **Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with ONGLYZA or any other antidiabetic drug
- **Most common adverse reactions** (regardless of investigator assessment of causality) reported in $\geq 5\%$ of patients treated with ONGLYZA and more commonly than in patients treated with control were upper respiratory tract infection (7.7%, 7.6%), headache (7.5%, 5.2%), nasopharyngitis (6.9%, 4.0%) and urinary tract infection (6.8%, 6.1%)
- When used as add-on combination therapy with a thiazolidinedione, the incidence of peripheral edema for ONGLYZA 2.5 mg, 5 mg, and placebo was 3.1%, 8.1% and 4.3%, respectively
- **Laboratory Tests:** There was a dose-related mean decrease in absolute lymphocyte count observed with ONGLYZA

Drug Interactions: Because ketoconazole, a strong CYP3A4/5 inhibitor, increased saxagliptin exposure, the dose of ONGLYZA should be limited to 2.5 mg when coadministered with a strong CYP3A4/5 inhibitor (e.g., atazanavir, clarithromycin, indinavir, itraconazole, ketoconazole, nefazodone, nelfinavir, ritonavir, saquinavir, and telithromycin).

Patients with Renal Impairment: The dose of ONGLYZA is 2.5 mg once daily for patients with moderate or severe renal impairment, or with end-stage renal disease requiring hemodialysis (creatinine clearance [CrCl] ≤ 50 mL/min). ONGLYZA should be administered following hemodialysis. ONGLYZA has not been studied in patients undergoing peritoneal dialysis. Assessment of renal function is recommended prior to initiation of ONGLYZA and periodically thereafter.

Pregnant and Nursing Women: There are no adequate and well-controlled studies in pregnant women. ONGLYZA, like other antidiabetic medications, should be used during pregnancy only if clearly needed. It is not known whether saxagliptin is secreted in human milk. Because many drugs are secreted in human milk, caution should be exercised when ONGLYZA is administered to a nursing woman.

Pediatric Patients: Safety and effectiveness of ONGLYZA in pediatric patients have not been established.

For more information about Onglyza, visit www.onglyza.com/one.

Please read the adjacent Brief Summary of the Product Information.



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