As ophthalmologists with EHR achieve the various Meaningful Use (MU) objectives to qualify for incentive payments, they may find several MU measures relate to the informed consent process, making proper documentation and the use of EHR more important than ever when patients agree to undergo a procedure.

Certain core and menu objectives for MU designed to ensure practices provide patients with information and timely access to records may assist physicians in complying with state informed-consent requirements. Moreover, as EHR adoption becomes more widespread, malpractice plaintiffs could use physicians’ failure to install EHR and achieve MU against them as evidence they are not complying with standard informed consent practices.

Here, I explain how EHR has changed the informed consent process and how to customize your procedure.

WHAT LACK OF INFORMED CONSENT MEANS
It can be separate from malpractice
In many states, lack of informed consent is a separate claim from medical malpractice. The elements of a lack of informed consent usually comprise the following:

• The physician was required to communicate some item of information, such as a risk or alternative, and failed to do so.
• The plaintiff or reasonable person would not have proceeded with the procedure had that item of information been known.
• The procedure caused the harm to the patient.

The typical EHR system does not incorporate a process for informed consent, whether for office-based or ASC procedures. Obtaining an informed consent is a legal requirement for elective invasive procedures in all states, but the documentation of that process and the patient’s understanding of it are left to the surgeon.

OBTAINING INFORMED CONSENT
Start with a discussion
In informed consent, the physician must first interact with the patient verbally and in person
and should not entirely delegate the process to staff. In cataract surgery, for example, the surgeon creates the incision, not the ophthalmic technician or optometrist. This interaction between patient and physician is essential.

Surgeons should embrace these opportunities with patients and use them to dispel unrealistic expectations, while earning the trust and gratitude that may result in more referrals. Verbal informed consent interaction should be done in a private setting with at least one witness, typically an employee. The discussion should focus on required information with a timely confirmatory note placed in the electronic record. The physician should encourage spouses and other family members to attend when the patient permits or the patient’s capacities require it.

Without this interaction, the patient sees the physician as just another staff member obtaining information. While private and public reimbursement policies have put demands on the physician’s practice time, the required interaction between physician and patient can still be done efficiently and documented electronically.

Supplementing the discussion
Proper documentation of informed consent includes the patient’s acknowledgment of the elements for informed consent the state requires. The surgeon must obtain the patient’s signature, preferably with a device that indicates the patient has been told of the elements and has read the consent information or been told of its content. The signature confirms the patient’s reading, understanding and the giving of consent.

While the culminating written consent is required, information leading up to the signing can be conveyed in any form, including verbally, or by video or pictures. For example, the AAO recently added its Retina Informed Consent Video Collection, made in conjunction with the Ophthalmic Mutual Insurance Company (OMIC). It features animations and explanations of the risks and benefits of procedures, such as retinal angiography and laser surgery for macular edema.

Informed consent is a process, not a document, so having different staff members deliver information in stages is appropriate. Still, the surgeon cannot entirely delegate his or her involvement at some step in the process.

In the states where I practice (New York, New Jersey), it is a requirement to document the date and time of the discussion, the patient’s acknowledgment of the required elements, and the names of the staff members involved in the consent.

Meaningful Use core objectives

1. Use computerized physician order entry for medication orders directly entered by any licensed healthcare professional who can enter orders per state, local and professional guidelines.

2. Implement drug-drug and drug-allergy interaction checks.

3. Maintain an up-to-date problem list of current and active diagnoses.

4. Generate and transmit permissible prescriptions electronically (eRx).

5. Maintain active medication list.

6. Maintain active medication allergy list.

7. Record all of the following demographics:
   - Preferred language
   - Gender
   - Race
   - Ethnicity
   - Date of birth

8. Record and chart changes in the following vital signs:
   - Height
   - Weight
   - Blood pressure
   - Calculate and display body mass index (BMI)
   - Plot and display growth charts for children 2–20 years, including BMI

9. Record smoking status for patients 13 years old or older.

10. Report ambulatory clinical quality measures to CMS, or in the case of Medicaid eligible professionals, the States. (No longer core objective but still required)

11. Implement one clinical decision support rule relevant to specialty or high clinical priority along with the ability to track compliance with that rule.

12. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, medication allergies) upon request.

13. Provide clinical summaries for patients for each office visit.

14. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.
New Jersey and Florida), the physician and staff must convey five categories of information to the patient in understandable terms with the opportunity to ask questions: patient’s condition, proposed treatment, risks, benefits and alternatives. Paper or electronic documentation is most legally effective when it contains these categories customized to the patient with the patient’s confirmation.

**Documentation**

When EHR is in place, practices often maintain informed consent documentation two ways: by scanning paper documents and uploading them to the patient’s electronic file, or by maintaining a separate paper file. Neither method is ideal as they do not use the potential of electronic technology.

Office-based consent documentation is best handled with electronic keypads for patient review and signature, and patient portals for access to charts and education. (**Box: “Informed consent documentation model”**) Patient access to office documentation and meta data evidence of their access is a good defense to the typical claim that information was not exchanged, and computer entries require patient actions confirming they have read the screen.

**Customization**

ASCs and hospitals have their own state and federal requirements, and their standard forms primarily protect their interests first and the surgeon’s second. Ideally, the surgeon needs a custom documentation process — the more customized, the greater the usefulness to patient and physician. Also, the more comprehensive the informed consent documentation and the patient input, the better. Well-documented consent forms take the steam out of malpractice claims by showing a judge or jury that a known complication can occur without malpractice.

Technology is a potential adjunct to the informed consent process, which must take place in a meaningful way (no pun intended) for a host of reasons. Customization of informed consent is not limited to addressing additional risks. Patients must know the physician is taking their daily functional needs into account, particularly for a purely elective procedure, such as LASIK, or a cosmetic one, such as blepharoplasty. A physician cannot go wrong in adapting a customized consent form to the patient’s own needs and concerns.

Some physicians have expressed concern that an informed-consent form, if too comprehensive, will scare away patients who should have surgery. But the physician is legally and ethically required to obtain informed consent, and patient hesitation rarely results in losing a patient or forever delaying a procedure, particularly when it is medically necessary.

**Utilizing patient portals**

Any EHR technology that benefits patients’ understanding and access to records or coordination of care with physicians contributes to MU while helping to comply with informed consent. Patient portals allow patients access to charts and patient education remotely. DialogMedical (Atlanta), iMedicWare (Old Bridge, N.J.) and Omedix (Scottsdale, Ariz.) incorporate keypad

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**Informed-consent documentation model**

A model for informed consent documentation should make retrieval, modification and patient and physician use easy for every invasive elective procedure. I suggest the following:

- Complete and execute the document before the day of the procedure if it will be performed at an ASC or hospital.
- The physician’s surgical administrator should have a library of consent documents for each type of procedure.
- The informed-consent form should contain the patient’s condition, proposed treatment, risks, benefits and alternatives. List additional specific risks for the particular patient, with the proviso that no document can contain a complete list of risks.
- The form should contain check boxes at each paragraph or point indicating the patient read that portion of the document.
- The form should contain a paragraph allowing the surgeon to take additional measures not contemplated that, in her or his judgment, are necessary to help the patient.
- The document may also require the patient to write or type an acknowledgment paragraph along with the signature. OMIC, for example, has a suggested cataract surgery consent on its website ([www.omic.com](http://www.omic.com)) that requires the patient to enter information, making it clear the patient has read the form.

Either paper or a computer interface can meet these requirements. The physician and a witness should sign and date after the patient executes the consent.

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patient input for informed consent documentation into their software.

Patient portals, like EHR, have their own privacy and liability issues. For example, portal messages can be discovered in litigation, and patients and office staff need to know their limited purposes. Some ophthalmologists have suggested patients sign a policy document that indicates they understand the role and limitations of portals.

Physicians who wish to comply with MU core and menu objectives need EHR capabilities to allow quick access to records without administration and copying costs. Offices that fully comply with EHR MU can easily document and prove they have established informed consent, especially if the practice actively engages patients to use portals to obtain their medical information.

**ELECTRONIC CONSENT BENEFITS**

**Patient convenience**

Electronic entry and execution of the informed-consent form has several advantages. After the form is introduced and explained at the office, patients can review it at home on the portal.

This approach allows for longer and more comprehensive forms, similar to LASIK consents. Patients aren’t rushed to read and execute the document at the office, and they can review and complete the form over several days. Electronic portals allow patients to interact and list questions for the next appointment, further confirming consent input and protecting the physician.

**Building relationships**

The bias of the Affordable Care Act toward centralized care giving and government reimbursement could make malpractice suits more common by reducing the consistency and quality of the relationship between the patient and the physician over time. Relationships make a difference in who gets sued.

If surgeons do not enhance the relationship, lawsuits are more likely when poor outcomes occur because the patient sees a revolving door of covering doctors or staff take on responsibilities. The informed consent discussion and documentation provide physicians with benefits on many levels.

**Protect yourself**

EHR technologies benefit physicians when the informed consent process is incorporated. Surgeons should use custom informed consent forms for every procedure, from office-based laser procedures to vitrectomies, to insulate them from malpractice suits without relying on hospital and ASC standard forms. Complications and poor outcomes can be defended at trial, especially when the informed consent form lists the complications and the patient signs it.

**REFERENCES**
