The State Operations Manual (SOM) is a federal publication that contains operating policies and procedures for state survey agencies charged with evaluating health care providers and suppliers and determining whether they are in compliance with federal health and safety standards. Although the Centers for Medicare and Medicaid Services (CMS) traditionally has maintained a paper-based SOM, CMS issued a new, internet-only version of the SOM in May 2004. The issuance of the internet-only version of the SOM received little fanfare in part because the health care industry assumed that it would simply be an electronic copy of the paper SOM.

Late last summer, however, state survey agencies began citing hospitals for surgical informed consent deficiencies based on new informed consent requirements buried in the internet-only SOM. Shortly thereafter, the existence of the new requirements spread by word of mouth and several national hospital associations and academic medical centers began to voice concerns regarding their ability to comply with the expanded informed consent requirements.

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2 See, e.g., CMS REVISES INFORMED CONSENT GUIDELINES, HEALTH LAW DEVELOPMENTS, DYKEMA GOSSETT (February 2005) (hereinafter, HEALTH LAW DEVELOPMENTS], available at http://www.dykema.com/healthcare/news/hlthlawdev0205.pdf (‘Providers were unaware of many of the changes, until surveyors began citing hospitals for failure to comply.”); GOVERNMENT NEWS OF THE WEEK: HIPAA, COMPLIANCE, AND OTHER FEDERAL AND STATE DEVELOPMENTS, AISHEALTH.COM (Jan. 25, 2005) [hereinafter, AIS Article], available at http://www.aishealth.com/GNOW/012405.html (noting that, “Survey[o]rs have been citing hospitals, and information about the changes has spread through word of mouth.”).
Hospitals that participate in the Medicare program have always been responsible for complying with the surgical informed consent requirements set forth in a group of regulations known as the Conditions of Participation for Hospitals (COPs). The surgical informed consent COP simply provides: “A properly executed informed consent form for the operation must be in the patient’s chart before surgery, except in emergencies.” The regulation neither specifies the health care practitioner (e.g., head surgeon, assisting surgeon, medical resident) who is permitted to engage in the informed consent dialogue with the patient nor appears to require informed consent forms to identify each and every individual who will participate in the surgical procedure. The Interpretive Guidelines set forth in the former, paper-based, SOM simply stated that, “A complete consent form should contain at least the following information . . . Name of practitioner(s).”

However, the Interpretive Guidelines set forth in the internet-only SOM now state that informed consent forms must contain, among other information, the:

Name of practitioner(s) performing the procedure(s) or important aspects of the procedures(s), as well as the name(s) and specific surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues). . .

The internet-only SOM further explains:

Furthermore, informed consent would include that the patient is informed as to who will actually perform surgical interventions that are planned. When practitioners other than the primary surgeon will perform important parts of the surgical procedures, even when under the primary surgeon’s

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3 The Conditions of Participation for Hospitals are codified at 42 C.F.R. Part 482. The surgical informed consent requirement is codified at 42 C.F.R. § 482.51(b)(2).
4 42 C.F.R. § 482.51(b)(2).
5 CENTERS FOR MEDICARE AND MEDICAID SERVICES, STATE OPERATIONS MANUAL, APPENDIX A, SURVEY PROTOCOL, REGULATIONS AND INTERPRETIVE GUIDELINES FOR HOSPITALS (Rev. 280, March 1997), at A-85 (on file with author); id. (Rev. 190), at A-90 (on file with author).
6 INTERNET-ONLY SOM, supra note 1, at A-0392.
supervision, the patient must be informed of who these other practitioners are, as well as what important tasks each will carry out.\textsuperscript{7}

The new language is controversial because, in academic medical centers, interns and residents frequently are assigned to observe or participate in surgical cases on an ad hoc basis shortly before surgery begins. For example, “a third-year resident may be scheduled for the surgery but wind up assisting in another procedure instead. Then a second-year resident is substituted.”\textsuperscript{8} Because assistance provided by surgical residents frequently includes opening and closing operative sites as well as dissecting, removing, and altering tissues, the internet-only SOM would require the names of these residents to be included in the informed consent form signed by the patient. However, many patients sign informed consent forms well before surgery when the identity of the particular residents who will be participating in the surgery is unknown.

The internet-only SOM further states that, “The responsible practitioner must disclose to the patient information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it.”\textsuperscript{9} Several hospitals also are concerned that the phrase “responsible practitioner” will be interpreted to permit only the head surgeon or attending physician to obtain the patient’s consent to the procedure (and to prohibit the delegation of the informed consent process to an assisting surgeon or participating resident).

In response to the concerns voiced by hospitals and academic medical centers across the country, CMS reportedly has indicated that it will further revise the SOM sometime in 2005 and that the “responsible practitioner” can delegate the informed

\textsuperscript{7} \textit{Id.}
\textsuperscript{8} AIS Article, \textit{supra} note 2.
\textsuperscript{9} INTERNET-ONLY SOM, \textit{supra} note 1, at A-0392.
consent dialogue to another surgeon, including a resident. Although it will be interesting to see how CMS finally resolves the issue, the current internet-only SOM provides a concrete example of how administrative agencies frequently adopt substantive requirements not through notice-and-comment rulemaking (which gives the industry charged with complying with the rulemaking an opportunity to respond), but through informal guidance that does not have the force or effect of law. Until CMS formally amends the internet-only SOM, many hospitals and academic medical centers are attempting to identify ways in which they can include in their consent forms the names of all practitioners who will perform significant parts of surgical procedures while attempting to ensure that medical residents continue to have a number of surgical opportunities each day.

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10 See, e.g., HEALTH LAW DEVELOPMENTS, supra note 2, at 4; Dennis Barry and Nancy LeGros, Follow-Up to Medicare Interpretive Guidelines on Informed Consent, HEALTH HEADLINES (Jan. 24, 2005) (“CMS has indicated, however, that the ‘responsible practitioner’ may delegate this task to another surgeon (including a resident) who will participate in the procedure. The agency is considering revisions to the Guidelines to address compliance difficulties identified by several national health organizations, in particular the requirement to inform patients prior to the surgery of the individuals who perform ‘important aspects of the procedure.’”).