

CME BRIEFING

NEWS, OPINIONS, AND PERSPECTIVES IN CONTINUING MEDICAL EDUCATION ~ SPRING 1999

A Service of Professional Postgraduate Services®, a division of Physicians World Communications Group

System98 Is Here

Just a few weeks have passed since System98, the new system for accreditation of CME providers and recognition of state organizations as accreditors of providers, was formally ratified by the parent organization members of the Accreditation Council for Continuing Medical Education (ACCME). But there's been a lot of buzz about System98 in the CME community for several months, as the draft document has been available for review since July 1998.

Starting in July of this year, the council will begin reviewing providers applying for accreditation (or reaccreditation) according to this new criterion-referenced process, which includes some changes in the data sources and methods that will be used to make accreditation decisions. The most obvious difference from the current Essentials and Standards is in the organization of

the document. Notably, where there had been seven Essentials and two Standards, there now are only three Essential areas, each containing from two to five related Elements of structure, method, and organization.

There also is a new approach to the recognition of exemplary compliance—the classification that indicates the provider exceeds expectations for compliance with individual Essential areas and Elements. For example, in Elements 2.4 and 2.5 of System98, providers can earn this status if they track and evaluate the effectiveness of their programs. This has proven to be one of the more controversial stipulations of System98, as many providers have interpreted it to mean that the new system will obligate them to conduct outcomes research on their CME offerings.

Given these changes, it's not surprising that many people in the CME community have been con-

cerned about the impact of System98 on their operations. That concern was reflected in the questions posed to ACCME staff at the recent 24th Annual Conference of the Alliance for CME (held January 27-30, 1999, in Atlanta, Georgia).

Some people worried that the new system might wreak havoc on their carefully constructed documentation systems, while others wondered what kind of support ACCME would provide to help them educate change-resistant faculty and board members about the new requirements. Still others despaired that, with their limited resources, they would not be able to implement the kind of outcomes analyses they assumed the new system would demand.

ACCME Promises Transition, Not Tumult

Representatives of the council attempted to calm these jitters, indi-

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Last summer, a federal court dismissed the last of what had been hundreds of liability claims filed since 1995 against several American medical societies in a mass tort action known informally as the "Pedicule Screw Case." The defendants in the court actions included the Academy of Orthopedic Surgeons, the American Association of Neurological Surgeons, the Scoliosis Research Society, and the North American Spine Society (NASS).

While the individual claims were ultimately deemed without merit, the tort action nevertheless cost millions of dollars to defend and established a new legal precedent under which CME providers could be held liable for harm allegedly caused by information disseminated at one of their programs. According to Shawn M. Collins, JD, an attorney who defended the NASS in the lawsuits, the cases were landmark in

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CME BRIEFING

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We are proud of our 25-year history of medical publishing, and feel a responsibility to enhance medical education by improving communication among interested parties. Our proactive relationship with the government, the medical profession, industry, and CME sponsors will benefit from the input of our readers.

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that they represented the first time plaintiffs had attempted to sue CME providers in a mass tort litigation. Collins has outlined the history of the case, which he believes to have important ramifications for all CME/CPE providers, at two major meetings in recent months. The first was the 9th Annual Conference of the National Task Force on CME Provider/Industry Collaboration held last September in Washington, DC, and, more

The cases were landmark in that they represented the first time plaintiffs had attempted to sue CME providers in a mass tort litigation.

— *Shawn M. Collins, JD*

recently, Collins spoke at the 24th Annual Conference of the Alliance for CME, January 27-30, 1999, in Atlanta, Georgia.

The Pedicle Screw Case

Beginning in 1994, a small group of attorneys began filing lawsuits on behalf of hundreds of individuals who had undergone orthopedic surgery involving pedicle screws, a medical device inserted into a patient's back to stabilize the spine. The lawsuits, which were initially filed against the manufacturers, alleged that the pedicle screw was unsafe and had caused the plaintiffs harm.

According to Collins, that action, whether one agrees with it or not, is consistent with what typically happens in product liability cases: device manufacturers are "the usual suspects" in these kinds of lawsuits, according to Collins.

Potential plaintiffs were recruited through newspaper ads suggesting that people who had received these devices might be entitled to monetary compensation and directing them to contact the attorneys organizing the class action. This, too, is a common—albeit controversial—tactic of mass tort litigation.

In late 1995, the plaintiffs' attorneys began pursuing cases against CME associations that had sponsored education activities where the use of pedicle screws was discussed. The cases alleged that in presenting information on what was, at that time, off-label uses of the pedicle screws, the associations had defrauded physicians who implanted the devices, and had therefore harmed the patients.

The associations' motives, according to the plaintiffs, lay in financial relationships between the associations' faculty and board members, and the manufacturers of the pedicle screws. In all, according to Collins, there were 500 cases involving the NASS, Collins' client.

NASS Defense Attacks Legal Theory

The defense's first step was to attack the legal theory of the plaintiffs. Under the First Amendment, the NASS legal team argued, the association has the right to host

The cases alleged that in presenting information on...off-label uses of the pedicle screws, the associations had defrauded physicians...and therefore harmed the patients.

CME events; further, it was their responsibility to host them, since free and open discourse is integral to valid medical research. The second argument was directed at the charge that the association had

defrauded the physicians attending their CME activities. The defense team asserted it is irrational to believe that educated physicians would choose to ignore their own clinical experience and instinct and perform inappropriate surgical procedures simply on the basis of a CME presentation.

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A federal court in Philadelphia discounted those arguments, saying that as long as the plaintiffs' allegations could be proven, the associations could be found liable. The Supreme Court has repeatedly said that commercial speech (ie, speech promoting a product) has less constitutional protection than other kinds of speech—for example, academic speech. If a financial relationship between an event's faculty members and the device manufacturers could be shown, the judge said, then the CME presentation in question could be seen as commercial speech rather than academic. That would mean that the producers of the speech could be found liable for saying things that were false, misleading, or reckless.

Plaintiffs' Cases Crumble for Lack of Evidence

According to Collins, it was then that the plaintiffs' cases began to break down. In an effort to expose the hollowness of the case, the association attorneys deposed the key expert witness produced by the plaintiffs' lawyers. "He was so concerned about his possible criminal behavior," said

Collins, "that he answered the first question, which was 'what is your name,' and then refused to answer the next 85 questions based on his Fifth Amendment privileges."

The defense team also began interviewing the physicians who had allegedly been defrauded by the associations. Hundreds of them, according to Collins, denied that they had been defrauded at all—and some reported that they had never attended a NASS seminar. At that point, said Collins, judges began throwing out plaintiffs' cases for lack of evidence. Eventually, the plaintiffs' attorneys themselves dropped the remainder of the suits.

Consequences for CME Providers

Even though NASS successfully defended itself, said Collins, the results are not all positive from the perspective of CME providers. "We look back on this, now that the suits are over," he said. "We won, and we feel very good about that. But ... a couple of things are sobering." For one, he said, the simple cost of defending itself was a burden for the association, which would have been forced to settle the case if it hadn't had adequate insurance

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coverage. Altogether, it cost about \$10 million to defend the medical societies in the pedicle screw cases, according to Collins. What's more, valuable time and energy were expended on the litigation.

But the most disturbing consequence, according to Collins, stems from the first federal court ruling, which set a new precedent: CME

providers are now open to being sued for things their faculty members have said, as well as things they have *not* said. While not likely to become a common occurrence, the fact that it can happen, according to Collins, is enough for CME providers to be concerned. "If the evidence fits the theory," he said, "you can be brought to court."

Are we likely to see a rash of lawsuits brought against CME providers? Collins says no, but counsels against complacency. "I think it's fairly unlikely, but when an unlikely event has such extraordinary costs associated with it, should

One key factor [in protecting against lawsuits] is clear separation of CME from promotional activities. The second...is disclosure, disclosure, disclosure.

it happen, then that's a good reason for us to think about how to stop it." He stressed, however, that there are a number of ways that providers can protect themselves against such suits (see *Seven Steps to Avoiding Liability in CME* on page 5). Of these, one key factor is clear separation of CME from promotional activities. The second indispensable step, according to Collins, is "disclosure, disclosure, disclosure."

Collins believes scientifically and clinically valid discussions, even if they involve off-label uses, are vital to the CME enterprise. "That's where people really get helped, that's where the action is, and that's what makes American medical research as good as it gets." But the disclosure of a drug's or device's off-label use is crucial for an organization to protect itself from liability. It is important, said Collins, not to rely on faculty members to make oral disclosures in their speeches. "Make

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sure it's there in print, or on the syllabus, so you can prove to the world later that it was disclosed."

Regarding financial relationships, Collins said, "Here is the test: If people were to find out later that [a speaker or faculty member] had a financial relationship [with a manufacturer], would they like to have known about it as they were listening

Financial relationships are not bad; undisclosed financial relationships may well be interpreted as such by Monday morning quarterbacks.

— Shawn M. Collins, JD

to him or her talking about the drug or device? Almost invariably, the answer is yes, so tell them." To protect themselves, CME providers should demand full disclosure from all of their speakers and faculty members.

In a more general way, said Collins, organizations should do everything they can to create a "culture of disclosure." Board members, for example, should disclose to each other any financial relationships, to set a tone in the organization. "It would be a misreading of the pedicle screw litigation to say, let's sever ties with manufacturers, let's not get involved with people who make money for a living," said Collins. "It is necessary, and will be increasingly necessary in the future as government gets more and more out of the business of funding education. That's the reality. The way we deal with it is disclosure. Financial relationships are not bad; undisclosed financial relationships may well be interpreted as such by Monday morning quarterbacks." ~

Seven Steps to Avoiding Liability in CME

In light of his experience defending the North American Spine Society against the pedicle screw mass tort litigation, Shawn M. Collins, JD, outlined seven steps CME providers should take to protect themselves from similar legal actions.

1. **Separate CME events from commercial activities.** For example, if a CME activity coincides with a promotional event, do as much as possible to separate the events in time, space, and sponsorship. The difference between the two should be immediately clear to an outside observer—not only at the time of the activity but also in retrospect. "Think to yourself about what is the overall character of this event," said Collins. "It is very easy, especially in hindsight, for a plaintiff's lawyer to characterize the entire event as commercial."
2. **Disclose both financial relationships and off-label discussions of drugs or devices.** All disclosures should be written and kept on file. "Make sure it's in the printed materials that get handed out at every one of your events," Collins advised. "The fact of [disclosure] and the proving of it are often two different things."
3. **Assess organizational conduct.** "Analyze the revenue sources of your organization, to see where the money's coming from," said Collins. "Are you disturbed at all about the percentages of money that you get from this organization, or this industry, or this group of organizations? Analyze your organizational conduct. Are you taking risks because you're getting a lot of money from somebody? If so, you've got to step back and say, 'What are we doing? Are we doing things here for the right reason?'"
4. **Carry adequate insurance.** Collins emphasized the importance of having a policy that covers not only any settlements or awards won by a plaintiff, but one that pays for legal expenses as well. "If it costs you \$10 million to prove your innocence, and you don't have \$10 million, that can cause you to settle the case when principle tells you not to," said Collins. "The bald truth is, if you cannot afford to defend yourself, it doesn't matter whether you're guilty or innocent."
5. **Follow your own rules.** In particular, said Collins, if an organization says an event is certified for CME credit, it must follow the ACCME Essentials and Standards; if an organization has its own rules, then it must follow them as well. "The easiest mark for any plaintiff's lawyer is an organization that sets up rules and says it follows them, and then doesn't. Whether those rules are your own internal rules, or the ACCME guidelines, if you're telling the world that you follow those, you'd better follow them."
6. **Keep your eye on the ball.** If an organization remembers what its true purpose is, whether teaching, research, or the communication of important information, it will be less likely to get into trouble, said Collins. "It will serve as a guideline for making decisions about important relationships and about the kind of events you can and can't get involved in," he said. A clear sense of focus will also help an organization make the difficult day-to-day decisions—for example, about requiring speaker disclosure.
7. **Don't be intimidated.** "The worst thing that could ever happen," he said, "would be for CME organizations to be intimidated and kowtow to the attorneys who bring lawsuits like this, and to kowtow to a system that doesn't deal with these cases expeditiously and fairly enough. Don't let that happen. There's too much at stake." Collins added that organizations should get involved with tort reform. In addition, they could set up internal rules to sanction physicians who give false testimony without reviewing a patient's medical records.

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cating that while the transition might involve some accommodation, the changes should not be wrenching. In one of several presentations on ACCME's current and new accreditation systems, the council's Assistant Executive Director, Kate Regnier, MA, MBA, observed that, for the most part, ACCME preserved the fabric of the old Essentials. According to Regnier, "A lot of [System98] is the old translated into the new, so it should be an easy transition...if you are currently in compliance."

In a presentation that compared the two systems (see *System98: What's New?* on page 6), Regnier emphasized that the primary intent of System98 is to clarify and streamline the ACCME Essentials and related policies. This has been achieved by

A lot of [System98] is the old translated into the new, so it should be an easy transition...if you are currently in compliance.

– Kate Regnier, MA, MBA (ACCME)

synthesizing the current Essentials and Standards into three Essential areas that eliminate some of the redundancy of the current system and, in effect, give individual providers more leeway to develop systems tailored to their particular institutional needs.

In the discussion session after Regnier's presentation, the first question focused on the nuts and bolts of the new system. "Although the system has been reworded, the substance seems the same," the questioner observed. She then continued by asking, "But how will this

translate in terms of my day-to-day filing and the documentation we do? Are you going to be looking for different forms of documentation in the files?"

Regnier responded that the exact paperwork required would depend on the specific wording of the ACCME application, which is still being written. "There will be some elements that you need to document and others that we will simply ask you questions about, just as with the present system," said Regnier. "But what you will probably want to do is sift through what you are currently doing and figure out what you must continue doing because it is required by ACCME and what you want to continue doing just because it is good practice."

Murray Kopelow, MD, Executive Director of the council, who also participated in the session, added that the goal of System98 is to emphasize the spirit of ACCME policies, not the letter of the law. "We would hope that the question of how this affects your documentation would not be the issue, but that you would look at this system and say, 'How does this affect how we practice CME?'" Kopelow continued, "The issue is not the quality of your *files*. The issue is the quality of your *events*. And by evaluating your effectiveness, you can find the areas where you want to improve." Dr Kopelow added, "When you do that, come to us and say, 'Here's how we have improved.'"

Evaluating Effectiveness: Outcomes Assessment in Disguise?

Despite assurances that the shift to System98 should not be too difficult, it is apparent that the council wants to raise the bar of excellence in CME. That goal is most clearly reflected in the requirement that providers must consistently measure the effectiveness of their activities for their compliance to be recognized as "exemplary." But several speakers questioned how many providers would be able to meet that challenge.

One representative of a specialty society said, "We can ask physicians whether they found the program valuable, or if it will change their practice, but we have no mechanism for going out and measuring what impact it really had. My board has passed a mandate that we do *not* do outcomes research, period, in any

The issue is not the quality of your files. The issue is the quality of your events. And by evaluating your effectiveness, you can find the areas where you want to improve.

– Murray Kopelow, MD (ACCME)

way, shape, or form. So I'm trying to figure out how we can comply."

Regnier noted that similar concerns had been raised at a meeting of MECCA, the Alliance special-interest group for members who represent commercial medical education and communications companies. "They asked themselves the same question, 'How are we going to assess satisfaction, knowledge, skill?'" One answer, according to Regnier, may be to partner with different organizations. As an example, Regnier suggested that providers who are not directly involved with patient care (such as state and specialty societies, as well as commercial providers) might conduct jointly sponsored activities with hospitals or contract with medical schools that have the resources to carry out this kind of research.

At least one person remained skeptical about how easily the requirement could be implemented. "Sometimes the ACCME reminds me of Congress," he quipped. "Many times, they legislate—but they don't appropriate the funds to conduct the activity." Having done outcomes research for many years, the participant asserted that it would raise the

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System98: What's New?

ESSENTIAL AREA 1: *Purpose and Mission*

ELEMENTS:

- 1.1 Written statement of CME mission (including CME purpose, content areas, target audience, type of activities provided, and expected results of program)
- 1.2 Demonstration of how CME mission is congruent with and supported by parent organization

COMMENTS/CHANGES FROM CURRENT DOCUMENT:

- Current requirement that mission statement indicate scope of CME effort is replaced by requirement that mission statement indicate content areas of activities
- New requirement that, if accredited provider is owned by parent organization, it must be able to demonstrate congruence and support from parent organization

ESSENTIAL AREA 2: *Educational Planning and Evaluation*

ELEMENTS:

- 2.1 Planning process(es) link identified and educational needs with desired result in provision of all CME activities
- 2.2 Needs assessment data used to plan CME activities
- 2.3 Communicate purpose or objectives of activity so learner is informed before participation
- 2.4 Evaluate effectiveness of CME activities in meeting identified educational needs
- 2.5 Evaluate effectiveness of overall CME program and make improvements to program

COMMENTS/CHANGES FROM CURRENT DOCUMENT:

- Current Essentials 2–5 (“education” Essentials) have been synthesized into one Essential area
- First two Elements deal specifically with the requirements for planning process and needs assessment
- Current Essential 3 has been refocused to requirement for communication of objectives to the learner prior to the activity
- New Elements 2.4 and 2.5 expand on requirements of current Essential 5, but details of how these evaluations should be conducted are left to discretion of provider

ESSENTIAL AREA 3: *Administration*

ELEMENTS:

- 3.1 Organizational framework for CME unit provides necessary resources to support its mission
- 3.2 Operate business and management policies/procedures of CME program so obligations and commitments are met
- 3.3 Present CME activities in compliance with ACCME’s policies for disclosure and financial support

COMMENTS/CHANGES FROM CURRENT DOCUMENT:

- As before, need to provide information about structure of the organization and its ability to fulfill its mission, including support from the parent organization (if a parent organization exists)
- One of the requirements in current Essential 6 is now ACCME policy: “An accredited sponsor will have mechanisms in place to record and, when authorized by the participating physician, verify participation.”
- Current Essential 7 (regarding joint sponsorship) no longer a line item because it is redundant: all activities, whether directly or jointly sponsored, must meet the same requirements
- Increased emphasis on importance of providing full disclosure for the learner, including financial relationships/support, off-label uses of drugs/devices, and identification of provider responsible for compliance; also clarification that disclosure policies apply even if provider does not accept commercial support
- Standards for commercial support are now specified in Element 3 of Essential area 3; the current standards have been incorporated with no change as Attachment 5 to System98
- Enduring materials are considered to be the same as any other CME activities; thus, they must comply with the Essential areas and their Elements, as well as with general ACCME policies and policies specific to enduring materials

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cost of CME to an unacceptably high level. "I'm not opposed to outcomes research," he insisted. "I do it as part of what I do in CME. But what I want to know is, who are you expecting to pay for it?"

I'm not opposed to outcomes research. I do it as part of what I do in CME. But what I want to know is, who [is ACCME] expecting to pay for it?

— Participant at Alliance for CME 24th Annual Conference

Kopelow countered this objection by pointing out that the word "outcomes" does not actually appear anywhere in the System98 document. "We tried very carefully to ensure that we didn't use that word," he said, "because nobody knows what it means except...that it's really expensive and it's really hard. So what we put in for exemplary compliance is 'Educational activities are evaluated consistently for effectiveness in meeting identified educational needs as measured by practice application and/or health status improvement.'"

Kopelow described the ACCME definition of "evaluation of effectiveness" as "pretty broad," adding that there are many organizations with systems already in place to produce the data. "Maybe we're talking about promoting partnerships, but we are [definitely] talking about identifying those things that we value more clearly." Kopelow also emphasized that providers can still be in compliance even if they do not carry out such assessments. "The point is not to take any punitive action against those that don't have the means and the budgets, but to provide a mechanism for recognizing the people who go the extra distance."

Providers Ask ACCME Support

Another participant said he hoped that the ACCME would continue to issue interpretive responses regarding the Essentials and Standards to help CME professionals communicate with faculty who may interpret their meaning differently. "Although I don't see anything that difficult in implementing System98," he said, "like everyone else, our physicians can be resistant to change."

Regnier asserted that the ACCME was committed to an ongoing dialogue to clarify and interpret their policies. "We have given thought to this. For example, a Q&A on our web site would be helpful. In addition, you can use our newsletter and our handouts that show the comparison between the old and new systems to educate your physicians." She added that ACCME staff is always available for consultation, including talking to providers and their boards via conference calls.

Kopelow added that System98 deliberately gives broad guidelines rather than precise statements about how the Essentials should be implemented. "We want to resist detail," he said. "We want to resist prescriptive language. That's what we did last time and we got ourselves into a pickle." He went on to explain that the specificity of the language in the current system might have promoted the idea that the paperwork was more important than the content of the programs.

"The analogy is that currently we take a blank piece of paper and we put an X on it. And we tell you this is how you have to do it. Now, we're giving you a blank piece of paper and putting a box on it and saying, 'Practice in here.'" But that does not mean there will be no limits, Kopelow said. "We will be clear about what the boundaries are—and we will tell you as you approach the limits. Your objective will be to move back, not to mediocrity, but toward safety and improving in another dimension."

Kopelow reaffirmed the council's commitment to facilitating providers' effectiveness by encouraging them to

practice the highest possible quality of CME. That commitment, he said, is validated by the adoption of System98 in January of this year. "The issue is the quality of your events and [the impact on] your learners and their patients that we are trying to promote," said Kopelow. "And if you find things that act as a barrier to your practicing CME, we need to hear that because we did all of this for that one reason." ~

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