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Lauded By Industry, Loathed By FDA? New HHS 'Good Guidance' Rule Likely Ruffling Feathers

by Shawn M. Schmitt

A Good Guidance Practices regulation from the US HHS, pushed through the rulemaking process in the waning days of the Trump administration, will likely delight the medtech industry and be pushed back on by the FDA, experts tell *Medtech Insight*.

A new final regulation on guidance documents pushed through the rulemaking process by the US Department of Health and Human Services (HHS) in the waning days of the Trump administration will likely be lauded by industry and loathed by the Food and Drug Administration.

The HHS – the overseer of the FDA, and 27 other agencies and offices – rolled out its *Good Guidance Practices* rule in the Federal Register on 7 December. The reg goes into effect on 6 January.

The department says its new rule is "designed to increase accountability, improve the fairness of guidance issued by [the HHS], guard against unlawful regulation through guidance, and safeguard the important principles underlying the United States administrative law system."

Guidance documents aren't legally enforceable. Rather, they lay bare an agency's current thinking on a particular subject.

The rule is also a piece of the HHS's *ongoing plans for broader regulatory reform*, the department says, and meets requirements laid out in an *October 2019 executive order* from President Trump on "Promoting the Rule of Law Through Improved Agency Guidance Documents."

The new rule calls for all guidance documents to be added to an *online repository* (which has already been populated by more than 30,000 entries), directs the HHS secretary to take a more hands-on approach to the docs, distinguishes so-called "significant" guidances from more traditional ones, and gives anyone the opportunity to petition the department to rescind or modify a guidance, among other actions.

> ***"Is [the guidance petition process] something that's going to be welcomed by the industry? I think the answer is absolutely yes." – Jaime L.M. Jones***

The rule's petition process is "consistent with the spirit of the administration's view of agency overreaching and the ability for stakeholders to have engagement in the process," Jaime L.M. Jones, a partner in the law firm Sidley Austin LLP, told *Medtech Insight*.

"The reality is that even pre this rule, there were less formal methods of engagement between industry and the relevant departments and agencies on all sorts of guidance issues," she said. "So now what we have is just a more formalized process for that engagement."

And that, Jones says, will be embraced by industry because the petition process offers a clear pathway for manufacturers and other stakeholders to lobby to have guidances yanked or changed.

"Is this something that's going to be welcomed by the industry? I think the answer is absolutely yes," she said. "And I think that stakeholders in all sectors of the industry – from health care providers to medical device manufacturers, to drug companies to insurance providers – will look to take advantage of this process going forward."

A stakeholder can ask for a withdraw or modification of a guidance, the department says, if the doc "imposes binding obligations" beyond what's required under statutes or regulations, an agency uses a guidance to improperly "create additional legal obligations," or an agency exempts a doc from the new rule.

The HHS has 90 days to respond to petitions under the rule; the department's responses will be posted to the online guidance repository. (As of 11 December, *only one document* out of thousands – a Centers for Medicare and Medicaid Services (CMS) guidance known as the "State Operations Manual" – has been rescinded because of a petition.)

There have long been gripes from industry about how the FDA handles its guidance documents, from using the docs to circumvent rulemaking, to issuing one after another to the point where many in industry simply can't keep up (and that was *before* the agency issued all of those emergency guidances because of the COVID-19 pandemic).

In April 2019 the Trump administration tried to slow the number of new guidances and rules going out the door by requiring agencies to submit such docs to the Office of Management and Budget (OMB) for review. (Also see "*'Major' Pain For FDA: Under OMB Directive, Congress Will Vote On So-Called 'Major' Rules, Guidance Docs*" - Medtech Insight, 12 Apr, 2019.)

“Agencies should not be creating new law outside of the notice-and-comment rulemaking process. So the petition process is really designed to allow industry stakeholders to raise their hands and say, ‘Look, in whatever this guidance document is, for example, this particular office or agency has not simply given their interpretation of what the existing law says. They’re going beyond and creating new obligations, and this isn’t the right process for that,’” Jones said.

“There has to be a forum for that kind of dialogue,” she said. “So by creating a single pathway – a public pathway – to have this dialogue, I think that just increases the transparency. And I think it’s actually good for stakeholders and consumers and everyone. But I don’t think that it’s subject to overuse any more so than the current avenues of informal dialogue or litigation.”

In an interview with *Medtech Insight*, Jessica Schubel, a senior policy analyst for the Center on Budget and Policy Priorities, said she’s concerned about what she calls “vague” language in the rule around the topic of petitions.

“While on one hand it’s appropriate for the department to institute a petition process, it’s unclear to me how that process is supposed to work and what criteria HHS is going to use in its review of these petitions,” she said. “It’s just very vague, and it’s creating an additional and significant amount of administrative burden when it’s totally unnecessary.”

Schubel is concerned that the petition process will sap resources from the HHS and its agencies at a time when they need to be tackling big issues, such as the pandemic.

“I think everyone is a loser in terms of having this reg finalized, because it’s implementing a process that is totally unnecessary,” she said. “But I don’t necessarily know in terms of the petition process if you can think about it in terms of winners or losers. Obviously industry lobbying groups – advocacy groups – that are more knowledgeable about sub-reg guidance and have the staff, time, bandwidth and resources to petition, will.”

Lawyer Warns Of FDA Pushback

While industry may be happy with the new HHS Good Guidance Practices reg, the FDA probably

won't be. The agency has *its own good guidance practices* that are now rendered moot thanks to the rule.

"FDA has long operated under its own set of good guidance practices regulations, and as [the] final rule clarifies, FDA will be subject to the requirements of [the] Good Guidance Practices final rule until the [HHS] secretary amends FDA's own good guidance practices regulations to conform to the requirements" of Trump's 2019 executive order, the HHS says.

That probably isn't going over well at the FDA, attorney Jones said.

"FDA often chafes at being constrained by HHS. So I can only imagine that they are going to react strongly to this piece of the rulemaking, and that in the new [Biden] administration, the new commissioner of FDA and the new chief counsel of FDA will push back very hard on any attempts to change their own good guidance practices," she said.

Online Guidance Repository's Hefty Price Tag

From the HHS Good Guidance rule:

"For 2020, HHS expended approximately $2.4m to develop the guidance repository. HHS expected annual costs for 2021 and 2022 to be about $1m.

"However, the department expects benefits to accrue as a result of the streamlined and clarified process for issuing guidance documents. The department anticipates that the public, and, in particular, regulated parties, will benefit from greater efficiencies and more transparency in how the department operates and regulates."

> ***"This is another example of how the Trump administration is trying to tie the hands of the incoming Biden administration by gumming up the works." – Jessica Schubel***

Jones went on: "FDA strongly believes in its own current good guidance practices and feels they're very robust. FDA also believes, particularly in the midst of a public health crisis, that it needs to be able to move very nimbly to issue guidance."

As of 11 December, the *FDA has issued 66 emergency guidance docs* since the pandemic began, across all commodities it regulates.

"There's a view held by some that agencies need to be able, nimbly, to put out guidance, and I think there may be fear that this rule will inhibit agencies' ability to do that. And probably that is most acute with respect to FDA," Jones said. "We should expect FDA to push back very hard on being subject to this rule going forward."

Dual Regs From HHS An Attempt To 'Gum Up The Works'?

The new rule from the HHS is just one of two regulations recently put forward by the department that will have a profound effect on guidances and regs put out by the FDA, the CMS, and others.

Under a November *draft rule* called Securing Updated and Necessary Statutory Evaluations Timely (SUNSET), the HHS would require its agencies to review all regulations every 10 years to determine whether they're still necessary. (Also see "*Most Regs Would Get 10-Year Reviews Under HHS Proposal*" - Medtech Insight, 5 Nov, 2020.)

The SUNSET rule, combined with the Good Guidance rule, is just the Trump administration's attempt to kick sand in the gears of HHS agencies before the president's one and only term ends on 20 January, policy expert Schubel charges.

Time Is Ticking To Get Guidances Into Repository

Guidance docs that aren't in the HHS online repository by 6 January will be considered rescinded, the Good Guidance rule says.

"If the department wishes to reinstate a rescinded guidance document, the department may do so only by complying with all of the requirements applicable to guidance documents issued after" 6 January, the regulation states.

And a warning from the rule: "HHS currently has discretion to rescind a guidance document without soliciting public feedback and, indeed, without even providing notice to regulated parties."

"This is another example of how the Trump administration is trying to tie the hands of the incoming Biden administration by gumming up the works, so to speak. You can think about these two regs as a two-pronged approach to accomplishing that goal of gumming up the works," she said.

"They waited until the 11th hour to issue both of these regulations, particularly the SUNSET rule," Schubel said. "They turned the comment period around very quickly."

The *draft version* of the Good Guidance rule was published in the Federal Register on 20 August. The HHS allowed only 30 days for comments, over objections from some stakeholders. Nevertheless, the department says that was enough time for people to review and comment on

the reg, which took up only six pages in the Federal Register. And despite that short window of time, the HHS still received 88 comments.

Meanwhile, the department gave stakeholders 60 days to comment on the SUNSET rule, which is more lengthy at roughly 29 Federal Register pages. The deadline for feedback on that reg is 4 January.

When it comes to the timing of the rules, "obviously there's an interest in making sure that they're carried out, and that their purpose is effectuated before the end of the administration," attorney Jones says, but she isn't convinced that the Trump administration's actions are nefarious.

"This administration has obviously pursued a number of initiatives to rein in attempts across agencies to make law through guidance," she said. "This is a small part of a much larger initiative that was very important to this administration. So it makes sense that they're going to take all of the steps they can to see it effectuated before the change in administration. There is probably some fear that the Biden administration would not carry through with the rules to the extent that this [current] administration would."

Jones isn't sure whether a Biden HHS would rescind the rules once the president-elect takes office.

"I suspect that there are going to be much higher priorities for the Biden administration than dealing with these particular rules," she said.

A Role For The HHS Secretary

The Good Guidance rule carves out a role for the HHS secretary to play, including signing off on all "significant" guidances.

The department in its rule defines a significant guidance as one that:

- Impacts the US economy to the tune of $100m or more annually;
- Adversely affects the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments, or communities "in a material way";
- Changes the "budgetary impact" of entitlements, grants, user fees or loan programs; or
- Raises "novel legal or policy issues arising out of legal mandates, the president's priorities, or the principles of [1993's] *executive order 12866*, "Regulatory Planning and Review."

The HHS says it expects few guidances will meet the significance threshold.

In fact, it's "HHS's presumption that a guidance document that HHS deems significant is actually a legislative rule that must go through notice-and-comment rulemaking," the Good Guidance rule says. "HHS shall make all initial decisions as to whether a guidance document is significant, and OMB shall make all final determinations."

Jones says it's "fair and appropriate" for an HHS secretary to review and approve guidance that would have a significant impact on industry.

"It's easy to dismiss some of this and say, 'Well, we're talking about just statements that agencies made. Why is this so important? Why would we be talking about even making a rule about this? Why would we get the secretary involved?'" she said.

"But things that, for example, CMS has included in notices to providers have shifted the way the entire health care system works because of the financial and enforcement consequences of whatever the statement is. And that's really what this whole initiative is designed to prevent," Jones added.

"When something is going to move an industry, or it's going to change the way health care gets delivered, or change the way technology gets reimbursed, or whatever, the hope is that that's the result of lawmaking, and not the result of bureaucrats in an office creating law."