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HHS finalizes rule that mandates exhaustive review of older regulations

by Robert King |
Jan 8, 2021

The Department of Health and Human Services finalized a rule that will require a massive review of all of its existing regulations. (Sarah Stierch/CC BY 4.0)

The Department of Health and Human Services (HHS) has finalized a rule that requires the agency to review all of its existing regulations and sunset any that don't meet certain criteria.

The final rule, released Friday, is a regulatory overhaul that could impact rules across the healthcare industry. Since proposing the rule in November, HHS made several changes intended to make it easier for the public to determine when a rule is under review and to comment on it.

"I do believe that by doing this it will be the boldest and most significant regulatory reform ever undertaken, for sure by HHS and also by the federal government," said Brian Harrison, HHS chief of staff, in an exclusive interview with *Fierce Healthcare*.

In a major change from the proposed rule, the final regulation gives HHS five years to review any existing regulations that are 10 years or older as opposed to two years under the proposal.

"There were a lot of folks that had questions about ability to do it in a period of time and resources required to do it," Harrison said.

There are a lot of regulations that would require a review in five years, as HHS estimated roughly 2,480 would need to be reviewed.

The rule would require HHS to review its regulations every 10 years to determine whether they must be reviewed by the Regulatory Flexibility Act, which requires agency inspection of certain rules. A review under the act includes whether a rule is still needed, whether it is duplicative or whether any technological or economic updates require rescinding it.

If HHS does not assess and review them in a timely manner, the rule will expire.

The rule does not apply to any HHS regulations that were jointly released with other agencies, any rules issued for military or foreign affairs issues or any on personnel matters. Annual payment rule updates such as those for hospitals and physicians are exempt; so are rules for the Medicare Diabetes Prevention Program.

The Notice of Benefit Payment Parameters, which outlines regulations each year for the Affordable Care Act exchange plans, also is exempt.

The final rule keeps those exemptions and includes a new exemption for any product-specific rules created by the Food and Drug Administration, according to an HHS subject matter expert who spoke with Fierce Healthcare.

"Many of the regulations we are exempting already have robust policies in place to provide periodic review," Harrison told reporters during a call Friday.

The rule has gotten severe pushback from some in the healthcare industry.

The American Hospital Association (AHA) said in comments that it could be confusing if a rule is up for review and when the public can comment. It criticized the rule's plan of setting up a website where if a deadline to review an assessment or a review is nearing, the public can submit a comment requesting the assessment to start.

The AHA gave an example of alternative payment models that get waivers of certain regulations such as the telehealth originating site requirement.

"If HHS unilaterally, and without public input, removed these waivers, modified them in an inappropriate manner, or let them inadvertently expire, it would cause confusion for participants and beneficiaries alike, and likely lead to failures of the program to achieve its goals," the AHA said.

In response to the concerns, each month HHS will post all new assessments and reviews in the Federal Register and enable comments on any such reviews.

"We are going to be setting up a dashboard where we will announce progress on assessing reviews," a subject matter expert said. "We will update folks on progress."

Long overdue – The Oracle.

The FDA issues Artificial Intelligence and Machine Learning (AI/ML) Software as a Medical Device Action Plan

Today, the U.S. Food and Drug Administration (FDA) issued the "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan" from the Center for Devices and Radiological Health's Digital Health Center of Excellence.

The Action Plan is a direct response to stakeholder feedback to the April 2019 discussion paper, "~~Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device~~" [SIC link is 404 now], and outlines five actions the FDA intends to take, which include:

Delphi Consulting Group, Houston, Texas 77071-3404
Contact: J. Harvey Knauss, +(832) 675-9281 voice, info@delphiconsulting.com or www.delphiconsulting.com

- Further developing the proposed regulatory framework, including issuing draft guidance on a predetermined change control plan;
- Supporting the development of good machine learning practices to evaluate and improve machine learning algorithms;
- Fostering a patient-centered approach, including device transparency to users;
- Developing methods to evaluate and improve machine learning algorithms; and
- Advancing real-world performance monitoring pilots.

AI/ML-based SaMD is a rapidly progressing field and the FDA anticipates this action plan will continue to evolve. The FDA welcomes continued feedback in this area and looks forward to engaging with stakeholders on these efforts. We will also continue to collaborate across the FDA to build a coordinated approach in areas of common focus related to AI/ML.

Inspections: GAO calls on FDA to plan for backlog, review alternatives

Posted 01 February 2021 | By Michael Mezher

In a nearly 350-page report to Congress on the federal government's COVID-19 response, the Government Accountability Office (GAO) calls on the US Food and Drug Administration (FDA) to review its inspections approach and come up with a plan to address its looming backlog.

Pandemic inspection alternatives

In the early days of the pandemic, FDA halted non-mission-critical foreign and domestic inspections and relied on alternative tools, such as inspection reports from foreign regulators, records requests and product sampling, to complement its oversight activities. The agency has since resumed some prioritized domestic inspections based on a rating system and, according to Acting Center for Drug Evaluation and Research Director Patrizia Cavazzoni's recent Twitter post, "FDA has begun conducting prioritized inspections by investigator staff in China and is planning to initiate prioritized inspections in India shortly."

Unsurprisingly, the pandemic has taken its toll on FDA's inspections program, cutting the number of drug establishment inspections the agency carried out in FYI2020 to less than half of what it had done in the previous two fiscal years. GAO says the drop in inspections has added to its "long-standing concerns about FDA's ability to oversee drugs manufactured overseas." (RELATED: *Do FDA's foreign offices help keep US drugs safe? GAO says answer is unknown*, *Regulatory Focus* 18 January 2017; *FDA defends its oversight of foreign drugs amid Senate, GAO criticism*, *Regulatory Focus* 3 June 2020).

"Prior to COVID-19, FDA typically conducted more than 1,600 inspections of foreign and domestic drug manufacturing establishments each year, but inspections have been reduced significantly. Alternative tools have helped FDA continue its oversight, but are not a comprehensive or long-term substitute for FDA inspections," GAO writes.

More than half of facilities that manufacture drugs for the US are located in other countries, with India and China being home to about a third of foreign drug establishments.

GAO found that from March, when FDA halted most foreign inspections, to September, the agency conducted just three "mission critical" foreign inspections: two for-cause inspections involving a Canadian hand sanitizer manufacturer and a German active pharmaceutical ingredient (API) maker, and one pre-approval inspection related to an Indian drugmaker's application for chloroquine phosphate tablets. In FY2018 and FY2019, FDA carried out more than 600 foreign inspections in the same span of time.

FDA also conducted just 52 domestic inspections from March to September, compared to about 400 in that time in each of the prior two years.

In FY2020, GAO found that FDA substituted inspection reports from European regulators for more than 160 inspection in Europe and asked for 30 reports from European regulators or Pharmaceutical Inspection Co-operation Scheme (PIC/S) members pertaining to establishments in China, India, Korea, Japan and elsewhere.

The extent that FDA can rely on inspections carried out by other regulators varies. "According to FDA officials, as of November 2020, FDA deemed that inspections conducted outside of Europe from 19 of 28 European regulators can be substituted for an FDA inspection. However, reports for inspections from the other 9 European regulators conducted outside of Europe and by PIC/S members can only be used to help obtain 'surveillance-level oversight' while inspections are paused and are not full substitutes for an FDA inspection," GAO writes.

The report points out that FDA's ability to rely on inspections carried out by its overseas counterparts may be limited going forward, as other regulators have also postponed inspections during the pandemic.

Foreign regulators may not be able to fill in the gap for inspections in two of the largest pharmaceutical export markets, India and China, where FDA typically conducts more foreign inspections than other regulators.

"Thus, there may not always be a foreign regulator report to rely on while FDA inspections are paused," GAO states, adding that in FY2019, FDA conducted nearly 1000 inspections in India and China.

FDA has also relied on alternative tools to compensate for its inability to conduct most preapproval inspections amid the pandemic. According to GAO, in FY2020 FDA made "over 130 requests for records and other information to support preapproval applications listing establishments in at least 27 countries."

Similarly, FDA made more than 310 requests for records and other information in lieu of surveillance inspections for establishments in 36 countries.

Recommendations and a new backlog

Based on its findings, GAO makes two recommendations to FDA related to inspections during and beyond the pandemic.

First, GAO calls on FDA to fully assess its alternative inspection tools and "consider whether these tools or others could provide the information needed to supplement regular inspection activities or help meet its drug oversight objectives when inspections are not possible in the future."

Second, GAO frets that a looming backlog of inspections could jeopardize the agency's strategic goal of shifting more of its inspections to a risk-based model and instructs the agency to assess its inspection plans for the coming years.

According to GAO, FDA has not fully assessed its alternative tools beyond reliance on European regulator inspection reports. "FDA has not assessed whether inspections conducted by PIC/S members are equivalent to FDA inspections. Thus, any establishments for which FDA uses PIC/S member reports for surveillance-level oversight during the COVID-19 inspection pause will still require an FDA inspection in the near future." But FDA officials told GAO there are limits to what it can use such alternative tools for. "For example, FDA officials told us that only FDA in-person inspections and European regulator reports can satisfy its statutory requirements for risk-based surveillance inspections."

Such an assessment could also inform whether any statutory changes "would allow [FDA] to more fully utilize alternative tools to meet its inspection responsibilities [and] increase the resilience of its drug manufacturing oversight going forward."

While FDA's new and generic drug approvals have continued apace during the pandemic and the agency has been able to meet its user fee agreement performance goals, there have been instances where the agency's inability to conduct an inspection has delayed decisions on products. (RELATED: *FDA details review timelines as facility assessment-related CRLs pile up*, *Regulatory Focus* 22 December 2020; *FDA approves fewer generics in FY2020, ending record streak*, *Regulatory Focus* 21 October 2020; *FDA sped progress for most of 2020's novel drugs*, *Regulatory Focus* 14 January 2021).

GAO and drug industry representatives interviewed for the report warn that a continued pause in preapproval inspections could lead to future delays in drug approvals.

GAO also expressed concern that the postponements could create a backlog of inspections of facilities that have never been inspected or that have not been inspected within five years. FDA considers such inspections to be mandatory and prioritizes the remainder of the inspections it carries out each year based on risk.

"The backlog of mandatory inspections this will create if inspections continue to be postponed could both extend the maximum interval between FDA inspections beyond FDA's 5-year policy and reduce the resources available in fiscal year 2022 for inspecting the other highest priority establishments identified by its model," GAO writes, noting that the agency has not yet finalized its surveillance inspection approach for FY2022, giving it an opportunity to assess its approach.

Brexit era: Working with a UK Responsible Person (UKRP)

February 18, 2021 | 9am CST

Our new webinar will address:
The current regulatory situation in Great Britain and Northern Ireland
Appointing a UK Responsible Person
Appointing an importer
Registration requirements
CE, UKCA and UKNI marking

Feb 18, 2021

The UK's withdrawal from the European Union has major ramifications for medical device manufacturers, including in-country representation requirements for companies selling their devices in Great Britain. Manufacturers will have to appoint UK Responsible Persons (UKRP) rather than European Authorized Representatives to manage their device registration and compliance efforts in the UK.

This webinar will be presented by Ronald Boumans, a Senior Consultant for Regulatory Affairs, with specific Brexit expertise. Ronald represents Emergo in the European Association of Authorized Representatives (EAAR) and represents EAAR at the European Commission in Brussels. He has also helped founding the UKRP Association, an organization that represents UKRPs and has frequent meetings with the British competent authority, MHRA.

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We are at last done with 2020, the lost year that seems to be still going in 2021. COVID-19 and mutations will control most of this year, however, there is light at the end of the tunnel. From our point of view things in Washington DC have improved. The Oracle looks forward to a good third and fourth quarters of 2021. Let's all hope.