

Diagnostics Developments and Supply Chain Issues



US CMS Providing Medicaid Coverage For COVID-19 Tests, But Congressman Still Sees Gaps For Testing Working Poor

Executive Summary

The US Centers for Medicare and Medicaid Services (CMS) created a new billing code to help diagnose coronavirus in its beneficiaries on 5 March, as well as fact sheets on medical care and transport of COVID-19 patients, but patients who get their health care through low-cost insurance plans may not be able to afford the testing, said a House Committee chairman.

The CMS has given health care facilities a billing code for its beneficiaries' coronavirus diagnostics – but working poor patients who have slipped through the cracks between Medicaid and Affordable Care Act coverage may find their “junk” plans don't cover the test, said Rep. Richard Neal, D-MA.

“At CMS, we continue to leverage every tool at our disposal in responding to COVID-19,” said CMS Administrator Seema Verma in announcing the new billing code for use by Medicare, Medicaid and Childrens' Health Insurance Program (CHIP) patients with coronavirus symptoms on 5 March. Verma added that the code would encourage physicians and laboratories to use the tests when needed.

The Healthcare Common Procedure Coding System (HCPCS) code provided by CMS, U0002, lets laboratories bill the Medicare agency for non-Centers for Disease Control and Prevention (CDC) tests. CMS in February released a HCPCS code – U0001 – to bill for the CDC-developed version of the diagnostic released on 4 February, but that code can only be employed by health care

facilities using CDC testing laboratories diagnosing suspected COVID-19 cases. (Also see “FDA Responds To Coronavirus By Getting Out First Emergency-Use Novel Coronavirus Diagnostic” - Medtech Insight, 4 Feb, 2020.)

“We are also providing critical information to our 130 million beneficiaries, many of whom are wondering what will be covered,” Verma said. The fact sheets detail Medicare, Medicaid, CHIP, and individual and small-group market private insurance coverage to help patients prepare for spread of the coronavirus.

For example, the fact sheets explain that in addition to diagnostic testing, Medicare covers all medically necessary hospitalizations, as well as brief telehealth check-ins, which allow patients and their doctors to connect by phone or text. They also note that ACA plans obtainable on HealthCare.gov apply to the diagnosis and treatment of covered patients with COVID-19.

Not All May Be Covered, House Ways And Means Chair Says

But not all insurance plans available to the working poor may cover coronavirus testing and treatment, warned House Ways and Means Committee Chairman Richard Neal, a Democrat from Massachusetts. In a letter to Verma posted on 6 March, he noted that patients with plans that do not comply with the Affordable Care Act may face either high out-of-pocket costs or uncovered services that prevent them from getting affordable COVID-19 testing.

“For individuals who have coverage under the non-ACA compliant plans, such as short-term

limited duration plans ... non-government lab tests for COVID-19 and the services related to administering the COVID-19 diagnostic tests are not required to be covered and can cost patients thousands of dollars," Neal wrote the CMS Administrator.

In a separate analysis by the Robert Wood Johnson Foundation, senior policy advisor Katherine Hempstead said that a very general estimate of an average emergency department

(ED) bill to diagnose flu-like symptoms has been pegged at \$1,100 by the Health Care Cost Institute, and that a recent visit by a Miami patient to a local ED for flu-like symptoms resulted in a \$3,200 bill.

Chairman Neal asked Verma in his letter whether the administration has already issued, or plans to issue, guidance on non-ACA compliant plans regarding testing and coverage of COVID-19, and requested a reply within two weeks.

COVID-19: Prepare For Medium- And Long-Term Health Care Supply Issues Says UK DHSC

Executive Summary

UK DHSC chief commercial officer Steve Oldfield addressed an 800-attendee webinar on health care measures being taken and supply chain issues recommended to control and contain coronavirus, which is now affecting 77 countries.

Injecting a “sense of urgency” was the aim of UK Department of Health and Social Care (DHSC) chief commercial officer Steve Oldfield, as he updated 800 attendees on UK coronavirus medicines and medtech supply chain issues during a special COVID-19 supply chain webinar on 4 March.

Coronavirus, now affecting 77 countries, is a matter of “absolute criticality” for the supply of medical goods, and the issue has long since evolved from being a China supply chain issue into a global one, he said.

The impact of COVID-19 is likely to come in waves, and while the short term effects are likely to be modest on supply chains and health care delivery, stakeholders should prepare for medium- and long-term impacts on supplies of medical devices, and cleaning and sanitation equipment etc, especially where export sources are located in touchpoint countries for coronavirus, Oldfield said.

Health care policy adopted in the UK, where 13,911 people have been tested for COVID-19 and 51 (as of 3 March) found to be positive (14 of whom have since recovered and been released from hospital care) is to promote “proportionate”

measures, i.e. not “do too much too soon that might provoke other problems.” Providers are advised against local stockpiling of personal protective equipment (PPE).

The DHSC has set up a continuity of supply response group, in a bid to take whole-system responses. It includes workstreams on devices and other health care products, and takes input from, among others, the Medicines and Healthcare products Regulatory Agency, Public Health England, and NHS England, which Oldfield said was “well prepared for such outbreaks.”

Beside the coronavirus action plan, launched by the prime minister on 3 March, the DHSC is spending much time mapping the advance of coronavirus, which is not yet declared a pandemic by the World Health Organization. The department holds daily meetings with health secretary Matt Hancock, and has input into the twice-weekly meetings of COBRA, the committee which coordinates the government’s response to crises that affect the UK. It also holds update calls with overseas counterparts daily.

Study Of Vulnerable Points Of Supply

The DHSC is also doing supply chain assessments to develop a clear picture of where the vulnerabilities lie in drug and devices supplies. The “single points of failure” in supply chain continuity are a cause for concern, said Oldfield. He has asked all health care players to conduct their own risk assessments of supply chains, including of their downstream suppliers of products and materials. The sense was that alternative supply sources will need to be sought wherever the chain breaks, be that in China or northern Italy, or any

other affected region.

The overall message at present is that there is no immediate concern for health care product supplies in the UK, but there would be medium- and long-term concerns over supplies, including of pharmaceutical active ingredients. (Oldfield said the UK is investigating the basis and legality of India's decision yesterday to ban exports of 26 pharmaceuticals due to fears over coronavirus-induced shortages locally.)

As coronavirus is a respiratory disease, many patients needing emergency care would require oxygen. PPE products will be a significantly constrained market, with gowns and masks in short supply and needing demand-management by providers.

Pending an escalation of cases, the official response from the DHSC is to continue business as usual as far as possible, ensure the sanitary measures announced in the coronavirus plan are adhered to, and share knowledge of any risks.

Coronavirus Crisis Highlights FDA's Device Supply Chain Blind Spots

Executive Summary

The ongoing COVID-19 crisis has shone a light on the US agency's inability to clearly see medical device supply chain troubles to help stave off product shortages. Unlike makers of pharmaceuticals and biologics, there's no requirement for device firms to tell the FDA if there's a particular event that could lead to a shortage – but that could change thanks to language found in the agency's fiscal year 2021 budget request.

The ongoing coronavirus crisis has shone a light on the US Food and Drug Administration's inability to clearly see medical device supply chain troubles to help stave off product shortages.

That's because – unlike makers of pharmaceuticals and biologics – there's no requirement for device manufacturers to tell the agency if there's a particular event that could lead to a shortage.

And what's even more head-scratching is that device companies can simply ignore FDA inquiries about possible disruptions to supply chains.

"Enabling the FDA to have timely and accurate information about likely or confirmed national shortages of essential devices would allow the agency to take steps to promote the continued availability of devices of public-health importance," FDA commissioner Stephen Hahn said in a late-evening statement released on 27 February.

He said language found in the agency's recently released fiscal year 2021 budget request would

help address shortages and the FDA's supply chain blind spots.

"FDA is seeking authority to: require firms to notify FDA of an anticipated significant interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide FDA with information about the manufacturing capacity of the essential device(s) they manufacture; and authorize the temporary importation of devices whose risks presented when patients and health care providers lack access to critically important medical devices outweigh compliance with US regulatory standards," the budget request says.

But until such measures are put in place, the FDA is taking "proactive steps" by engaging with device manufacturers, hospitals and group purchasing organizations to identify supply chain hiccups, Hahn explained.

"We are aware of 63 manufacturers which represent 72 facilities in China that produce essential medical devices; we have contacted all of them," he said. "We are aware that several of these facilities in China are adversely affected by COVID-19, citing workforce challenges, including the necessary quarantine of workers."

There are more than 11,000 manufacturers of class II and III devices in China.

An industry expert in Shanghai recently told Medtech Insight that exports of components and devices coming from China will continue to flow to the US and other countries for now, but there could be trouble soon if government quarantines

and international travel bans remain in place. (Also see “Chinese Device Exports, Supply Chains Holding Up In The Face Of Coronavirus – For Now” - Medtech Insight, 6 Feb, 2020.)

While FDA chief Hahn confirmed that there have been no reported shortages to date, he nevertheless noted that there has been an “increased market demand” in protective medical equipment such as surgical gowns, gloves, masks and respirators.

Hahn urges device makers and health care facilities to let the agency know if they’re facing shortages by emailing deviceshortages@fda.hhs.gov.

“This mailbox is closely monitored and has proven

to be a valuable surveillance resource to augment FDA efforts to detect and mitigate potential supply chain disruption,” he said.

The agency has become increasingly concerned about device shortages over the past year, particularly in light of the shutdown of several ethylene oxide (EtO) sterilization plants in the US.

Those EtO facilities were either temporarily or permanently closed because of concerns from stakeholders about the potential risk of increased cancer around the plants. The device industry and the FDA have cautioned, however, that closing the plants could lead to shortages. (Also see “US FDA Experts Caution Against Banning EtO, Encourage More Duodenoscopy Training” - Medtech Insight, 8 Nov, 2019.)

[For full coverage on Coronavirus from Medtech Insight, please click here](#)