Multi-Cancer Bill Likely Passes By Year-End

CMMI Cancer Pilot Underwhelms, Cancer Moonshot Refresh Coming & Sleeper Patent Bill

We provide our key takeaways from Summer Webinar #4, a Capitol Street fireside chat with Jennifer Leib, ScM, CGC, founder of Innovation Policy Solutions. Contact us if you need Replay or Slides.

- **There is strong bipartisan support for the *Medicare Multi-Cancer Early Detection Screening Coverage Act* this year.** This is helpful for Guardant (GH), EXACT Sciences (EXAS) GRAIL, in addition to other liquid biopsy/early cancer screening companies. Liquid or blood based biopsy tests that screen for multiple cancers have tremendous bipartisan and bicameral support. The Act would create a benefit category for multi-cancer screening tests for Medicare. The Senate bill has 50+ supporters, while the House side companion bill has 200+ representatives supporting it.

- **There is no Congressional / corporate opposition for this new Medicare screening coverage category**. The House is 40 sponsors away from the bill circumventing the committee passage and being discharged to the floor for a vote. There is a real possibility of expedited movement in Congress and potential for 4th quarter passage. The bill (here) does the following:
    - Creates the authority for CMS to cover blood-based multi-cancer early detection tests and future test methods (like urine or hair tests), once approved by the FDA. [Congress has acted before to create coverage for other cancer screenings including mammography and colorectal screenings]
    - Maintains CMS' authority to use an evidence-based process to determine coverage parameters for these new tests.
    - State that these new tools will complement, not replace, existing screenings and coverage and cost sharing will not be impacted.

- **Our guest speaker has two concerns with the pan-cancer screening bill discussed above that could pass by year end (H.R. 1946/S. 1873).** (1) Conflict with the VALID Act**.** Under the VALID Act, most tests would fall under tech cert, which does not use the phrase "cleared or approved." However, the Multi-Cancer bill only provides coverage for tests that are "cleared or approved" by the FDA. If this bill were to be passed with the VALID Act, there would be a coverage category that does not apply to IVCTs under VALID. This is an easy fix if the VALID Act were to move. (2) Lack of clarify referring to cancer types. Stakeholders are worried that the Act cites the early detection of cancer among "many" cancer types, without defining the term at all. How many cancers are covered? Is it 2 or more?

- **The Senate Diagnostic regulatory pathway bill -- VALID Act -- is unlikely to pass with FDA User Fees, and the 2027 policy may be tabled for now.** The VALID Act lacks the widespread bipartisan support needed to pass and User Fees may no longer be a viable vehicle for passing the VALID Act. It is possible that VALID could be added to Appropriations or other legislation (Cures 2.0, Pandemic Preparedness) moving this year. User Fees need to be passed by the end of September, and we anticipate a "clean" bill. The VALID Act remains controversial: Concerns raised include haziness around the interpretation of risk, as the policy currently breaks it down into low, moderate and high, but test developers interpret these scenarios differently from regulators.

- **New CMS Enhancing Oncology Care version 2.0 excludes genetic testing & has lower payment rates.** The demonstration covers seven (7) cancers (breast, lung, prostate, lymphoma, leukemia, multiple myeloma, and colorectal cancer), where precision medicine plays an outsized role. Since the episode of care begins only at treatment, the model does not allow patients to reap

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the benefits of genetic testing, which can play a crucial role in shaping treatment decisions. CMS pilot payment rate is lowered from $160 to $70 PMPM, which is unattractive to many oncology practices. Oncologists would receive an incremental $30 for dual eligible patients. Also, there is a one-year gap until the new model begins July 2023.

- **CMMI is open to feedback on the model, so EOM may not be final.** The agency may not have realized that somatic testing predates treatment and is not included in this model. There is hope for CMMI to address the lack of focus on precision medicine.

- **Sleeper Issue: *Patent Eligibility Restoration Act* has potential for causing dramatic changes.** Introduced by Senator Tillis (R-NC) the patent bill proposes wiping past case law, including SCOTUS decision (Myriad) about patent eligibility. The bill would *allow* patents on all naturally occurring substances and biomarkers and their association with health status. The Patent Office has a docket open until September 15 on the topic. If passed, the diagnostic world and interpretation of patent protections would change drastically. Odds of passage this year are low. The bill will likely be reintroduced next year. In general, Biotech and pharma companies support the legislation. Diagnostic companies mainly oppose.

- **Cancer Moonshot headlines will begin: Opportunities for private organizations.** While the administration has announced overarching goals, relating to promoting health equity and ending cancer, details have not yet been defined. Agencies (HHS, NIH, FDA, CMS.) working on Moonshot are looking for big ideas and public-private partnerships to define the future of the Moonshot. Biden will give a refresh speech next week.

- **Appointment of a new NCI Director holds promise for precision medicine.** Pres. Biden has announced that Dr. Monica Bertagnolli will be the 16th and first woman director of the National Cancer Institute. Her appointment coincides with the nation's renewed attention to cancer prevention and treatment, due to Cancer Moonshot.

- **Monkeypox PHE adds to ongoing COVID-19 challenges, and we are not seeing the US government use lessons learned from COVID.** There are industry concerns that government players are not applying lessons related to pandemic preparedness, supply chain issues and building testing capacity learned from COVID. FDA is on board with consolidation in the laboratory testing space. Although CDC has put out messaging that encourages test development, FDA has only authorized one test and announced that it will not take enforcement action against laboratories not using the CDC protocol. HHS has contracted with 5 laboratories to offer testing. In case the COVID PHE is not extended, FDA has already offered guidance to require tests with EUAs to acquire full compliance approval.

- **OUR TAKE/NEXT STEPS:** The VALID Act is unlikely to pass with the FDA User Fee Reauthorization, which is due before September 30. We think that the UFA bill will pass this fall. The *Multi-Cancer Screening Act* (GH, EXAS, GRAIL + others) could pass by year end. We are watching to see what will come out of ARPA-H (not much so far) and the Biden administration's Cancer Moonshot initiative; we anticipate public facing events and public-private partnership (PPPs) announcements over the next 12 months, particularly as a way to generate headlines and wins after the midterm election. Pres. Biden is scheduled to deliver a Moonshot speech next week. The *Patent Restoration Act* lacks momentum to pass at this time. CMMI could tweak the EOM model to provide a greater focus on precision medicine, before the start date for the next generation Oncology Care Model, which is July 2023. NOTE: If you missed our Summer Policy Webinar #4, contact us for a link to the replay, slide deck.

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