Federal Health Update

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Welcome to Federal Health Update. This newsletter is a compilation of the latest news in the federal health care sector.

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EXECUTIVE AND CONGRESSIONAL NEWS

- **On Jan. 20, 2017, Donald Trump will be sworn in as the 45th president of the United States.**

- **The Senate is expected to confirm General James Mattis as Secretary of Defense on Jan. 20, 2017.**

MILITARY HEALTH CARE NEWS

- **TRICARE and Military OneSource are co-hosting a webinar to educate TRICARE beneficiaries about their options for getting prescription medications.**

  The webinar is scheduled for Wednesday, Jan. 25, 2017, Noon-1:00 p.m. ET. The speaker for this event is Dr. George Jones. Jones is a retired Air Force colonel and now serves as the chief of Pharmacy Operations in the Defense Health Agency (DHA). The DHA Pharmacy Operations Division manages the TRICARE Pharmacy benefit for 9.4M beneficiaries with an annual cost over $8 billion.

The TRICARE Pharmacy Program provides four convenient ways for beneficiaries to get their prescriptions filled; through military pharmacies, TRICARE Pharmacy Home Delivery, TRICARE network retail pharmacies and non-network pharmacies.

To register for the webinar, please visit: https://attendee.gotowebinar.com/register/9211568059652614914. Registration is on a first-come, first-served basis and is limited due to system capacity. Participants must avoid sharing personal health information when asking a question. Beneficiaries on DoD networked computers, may also join us at https://conference.apps.mil/webconf/TRICAREPharmacy. For audio, please dial dial 1-866-724-3083, access code 1085851.

To learn more about TRICARE's Pharmacy Program, go to the Pharmacy page of the TRICARE website.

VETERANS AFFAIRS NEWS

- **The Department of Veterans Affairs (VA) announced that it is amending its regulation regarding fertility counseling and treatment available to eligible veterans and spouses.**

  VA currently provides certain infertility services other than in vitro fertilization (IVF) services to veterans as part of the medical benefits package. This interim final rule authorizes IVF for a veteran with a service-connected disability that results in the inability of the Veteran to procreate without the use of fertility treatment. It also states that VA may provide fertility counseling and treatment using assisted reproductive technologies (ART), including IVF, to a spouse of a Veteran with a service-connected disability that results in the inability of the Veteran to procreate without the use of fertility treatment.

  As part of the medical benefits package, VA provides many different types of fertility treatments and procedures to veterans. These include infertility counseling, laboratory blood testing, surgical correction of structural pathology, reversal of a vasectomy or tubal ligation, medication, and various other diagnostic studies or treatments and procedures

  Full implementation of this regulation requires that VA utilize and optimize existing capabilities for care in the community and develop internal processes that will provide veterans with a seamless path to receiving ART services. Veterans can immediately schedule appointments with their local health care system for eligibility determinations, clinical evaluation and consultation, and initial treatment as we work to build this structure.

  The interim final rule was published in the Federal Register on January 19, 2017 and can be accessed here. Although the interim rule references Sept. 30, 2017, as the date the funding expires, the funds are authorized through Sept. 30, 2018.

- **The Department of Veterans Affairs (VA) has published regulations to establish presumptions for the service connection of eight diseases associated with exposure to contaminants in the water supply at Camp Lejeune, N.C.**

  The presumption of service connection applies to active duty, reserve and National Guard members who served at Camp Lejeune for a minimum of 30 days (cumulative) between Aug.1, 1953 and Dec. 31, 1987, and are diagnosed with any of the following conditions:

  - adult leukemia
  - aplastic anemia and other myelodysplastic syndromes
  - bladder cancer
  - kidney cancer
  - liver cancer

- multiple myeloma
- non-Hodgkin's lymphoma
- Parkinson's disease

Environmental health experts in VA's Technical Workgroup conducted comprehensive reviews of scientific evidence, which included analysis and research done by the Department of Health and Human Service's Agency for Toxic Substances and Disease Registry (ATSDR), the Environmental Protection Agency, the International Agency for Research on Cancer, the National Toxicology Program, and the National Academies of Science.

Veterans with 30 or more cumulative days of active duty service, at Camp Lejeune during the contamination period are already eligible for certain medical benefits, following passage of the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012.

In the early 1980s, volatile organic compounds, trichloroethylene (TCE), a metal degreaser, and perchloroethylene (PCE), a dry cleaning agent, as well as benzene and vinyl chloride, were discovered in two on-base water supply systems at Camp Lejeune. The contaminated wells supplying the water systems were shut down in February 1985.

The area included in this presumption is all of Camp Lejeune and MCAS New River, including satellite camps and housing areas.

The rule will be effective either 60 days after publication in the Federal Register, or following conclusion of the 60-day Congressional Review, whichever is later.

GENERAL HEALTH CARE NEWS

- **The U.S. Department of Health and Human Services and 15 other federal agencies issued a final rule to update regulations that safeguard individuals who participate in research.**

Most provisions in the new rule will go into effect in 2018.

The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment.

The current regulations, which have been in place since 1991, are often referred to as the "Common Rule." They were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data has become digital.

In September 2015, HHS and the other Common Rule agencies published a Notice of Proposed Rulemaking (NPRM), which drew more than 2,100 comments. In response to concerns raised during the extensive review process, the final rule contains a number of significant changes from the proposed rule, including the removal of a provision that would have required researchers to obtain consent before using a study participant's non-identified biospecimens. The final rule maintains the current practice with respect to oversight of these specimens.

The final rule will now generally expect consent forms to include a concise explanation – at the beginning of the document – of the key information that would be most important to individuals contemplating participation in a particular study, including the purpose of the research, the risks and benefits, and appropriate alternative treatments that might be beneficial to the prospective subject.

Important elements in the final rule issued include:

- The requirement for consent forms to provide potential research subjects with a better understanding of a project's scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies. The proposal from the NPRM has been modified, however, to add substantial increased flexibility in now allowing broad groups of studies (instead of just specific studies) to be removed from this requirement.
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules.
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.
- Requirement that consent forms for certain federally funded clinical trials be posted on a public website.

Medical advances would not be possible without individuals who volunteer to participate in research. Oversight and protection of research participants is an important safeguard and essential to advancing the research enterprise.

To view the final rule, click here.

- **CDC's National Institute for Occupational Safety and Health (NIOSH) launched a new mobile application (app) that will measure sound levels in the workplace to help workers learn about their noise exposure and reduce the chances of hearing loss.**

  NIOSH estimates that 22 million workers are exposed to hazardous noise levels every year. In addition to damaging workers' quality of life, occupational hearing loss carries a high economic burden. An estimated $242 million is spent annually on workers' compensation for hearing loss disability.

  The new app is designed to assist industrial hygienists, occupational safety and health managers and workers who may not have access to professional sound measurement instruments to measure noise levels on the spot. The app is also designed to help raise awareness among workers about their work environment, especially those in the construction and the service industries (including musicians, teachers, and restaurant workers).

  The app is easy to use. It can serve as a practical tool that collects noise exposure data. The app provides a readout of the sound level in the workplace using either the built-in microphone or an external microphone and reports the instantaneous sound level in weighted decibels.

  When the user presses the PLAY button to collect sound levels, excluding conversations, the app stores the data collected on the user's device for downloading and sharing with managers or occupational safety and health staff. The app also provides important information about noise and hearing loss prevention.

  NIOSH establishes recommended exposure limits (REL) for various hazards based on the best available science and practice. The REL for noise is 85 decibels, as an 8-hour time-weighted average. Exposures at or above this level are considered hazardous to a worker's hearing.

Researchers hope that increased awareness could lead workers and managers to request professional noise surveys and to implement engineering controls or hearing conservation programs to reduce the risk of noise-induced hearing loss.

For more information, please visit the NIOSH Noise and Hearing Loss Prevention topic page.

To install the NIOSH Sound Level Meter app on your iOS device, visit: https://itunes.apple.com/us/app/niosh-slm/id1096545820?mt=8.

- **The Department of Health and Human Services released new information that shows that millions of seniors and people with disabilities with Medicare continue to save on prescription drugs and see improved benefits in 2016 as a result of the Affordable Care Act.**

  More than 11.8 million Medicare beneficiaries have received discounts over $26.8 billion on prescription drugs – an average of $2,272 per beneficiary – since the enactment of the Affordable Care Act. In 2016 alone, over 4.9 million seniors and people with disabilities received discounts of over $5.6 billion, for an average of $1,149 per beneficiary. This is an increase in savings compared to the 2015 information released this time last year, when 5.2 million Medicare beneficiaries received discounts of $5.4 billion, for an average of $1,054 per beneficiary.

  Medicare beneficiaries also continue to take advantage of certain recommended preventive services with no coinsurance:

  - An estimated 40.1 million people with Medicare (including those enrolled in Medicare Advantage) took advantage of at least one preventive service with no copays or deductibles in 2016, slightly more than in 2015.
  - More than 10.3 million Medicare beneficiaries (including those enrolled in Medicare Advantage) took advantage of an Annual Wellness Visit in 2016. Looking just at original Medicare, nearly one million more people utilized an Annual Wellness Visit in 2016 than 2015 (more than 6.6 million compared to nearly 5.8 million).

  The Obama Administration's goal to tie more than 30 percent of fee-for-service payments by the end of 2016 through alternative payment models to quality and cost metrics. Medicare is on pace to reach 50 percent by the end of 2018.

  The Affordable Care Act makes Medicare prescription drug coverage more affordable by gradually closing the gap in coverage during which beneficiaries had to pay the full cost of their prescriptions out of pocket, after hitting their initial coverage limit, and before catastrophic coverage for prescriptions took effect. The gap is known as the donut hole. Because of the Affordable Care Act, the donut hole has been narrowing each year, and will be closed by 2020.

  Because of the health care law, in 2010, anyone with a Medicare prescription drug plan who reached the prescription drug donut hole received a $250 rebate. In 2011, beneficiaries in the donut hole began receiving discounts and savings on covered brand-name and generic drugs. People with Medicare Part D who are in the donut hole in 2017 will receive discounts and savings of 60 percent on the cost of brand name drugs and 49 percent on the cost of generic drugs.

  For state-by-state information on discounts in the donut hole, go to: https://downloads.cms.gov/files/Part%20D%20Donut%20Hole%20Savings%20by%20State%20YTD%202016.pdf.

  For more information about Medicare prescription drug benefits, go to: http://www.medicare.gov/part-d/.

REPORTS/POLICIES

- **The GAO published *"Medicare Advantage: Limited Progress Made to Validate Encounter Data Used to Ensure Proper Payments,"* (GAO-17-223) on Jan. 19, 2017.** In this report, GAO identifies steps CMS has taken to validate MA encounter data, and CMS's plans and time frames for using MA encounter data—as well as stakeholder perspectives on these steps and plans. http://www.gao.gov/assets/690/682145.pdf

- **The GAO published *"National Institutes of Health: Kidney Disease Research Funding and Priority Setting,"* (GAO-17-121) on Jan. 18, 2017.** This report describes (1) the level of NIH funding for biomedical research on kidney disease, and for other leading diseases and conditions; and (2) how NIDDK sets priorities for kidney disease research. http://www.gao.gov/assets/690/681714.pdf

HILL HEARINGS

- There are no health-related hearings scheduled next week.

LEGISLATION

- **H.R.537** (introduced Jan. 13, 2017): To amend the Internal Revenue Code of 1986 to provide an exemption to the individual mandate to maintain health coverage for individuals residing in counties with fewer than 2 health insurance issuers offering plans on an Exchange; to require members of Congress and congressional staff to abide by the Patient Protection and Affordable Care Act with respect to health insurance coverage; and for other purposes was referred to House Oversight and Government Reform Sponsor: Representative Andy Biggs [R-AZ-5]

- **H.R.521** (introduced Jan. 13, 2017): To amend the Internal Revenue Code of 1986 to provide an exemption to the individual mandate to maintain health coverage for individuals residing in counties with fewer than 2 health insurance issuers offering plans on an Exchange was referred to the House Committee on Ways and Means. Sponsor: Representative Mark E. Amodei [R-NV-2]

- **S.147** (introduced Jan. 17, 2017): A bill to prevent a taxpayer bailout of health insurance issuers was referred to the Committee on Health, Education, Labor, and Pensions**.** Sponsor: Senator Marco Rubio [R-FL]

MEETINGS

- HIMSS 2017 Annual Conference will be held on **Feb. 19-23, 2017**, in Orlando, Fla. http://www.himssconference.org/
- The Heroes of Military Medicine Awards will be held on **May 4, 2017,** in Washington, DC. http://www.hjfcp3.org
- The 7th Annual Traumatic Brain Injury Conference will be held **May 24-25, 2017**, in Washington DC. http://tbiconference.com/home/

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