House File 387 - Introduced

HOUSE FILE 387
BY TUREK

A BILL FOR

An Act creating the better caths for Iowa Act including a review of the use and reimbursement of certain catheters under the Medicaid program.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. SHORT TITLE. This Act shall be known as the "Better Caths for Iowa Act".

Sec. 2. FINDINGS. The general assembly finds all of the following:

1. Di(2-ethylhexyl)phthalate (DEHP) belongs to a family of chemicals called phthalates: toxic, endocrine-disrupting chemicals which are added to certain plastic products to increase their flexibility. There is no question that the use of DEHP in medical devices harms patients. The evidence of patient exposure to DEHP and other toxins during the course of clinical care is well established and science continues to demonstrate the need to reduce patient risk from such exposure.

2. Exposure to phthalates like DEHP can do lasting harm to child brain development and increases children's risks for learning, attention, and behavior disorders.

3. A pregnant woman's exposure to phthalates, which is known to decrease fetal testosterone, can harm reproductive tract development in male babies which may have lifelong consequences.

4. Phthalates in medical devices like catheters have been shown to leach into soft tissue from the plastic, a reason phthalates have been banned in children's toys by the United States food and drug administration (FDA) as children often hold toys or put them in their mouths for long periods of time.

5. Exposure to phthalates can come from multiple sources simultaneously, including from food and food contact substances and other products. Therefore, assessing risks from individual phthalates may underestimate the health risks from exposure to mixtures of phthalates.

6. Research shows that women have higher exposure to phthalates found in care products than men.

7. Studies have shown that African American and Latina women have higher exposure to certain phthalates compared with white women.

8. In a nationally representative sample, African

American women had higher exposures to a real-world mixture of hormonally active phthalates compared with white women.

9. Studies have shown that people with disabilities who use catheters experience bladder cancer at four times the national average.

10. A population-based retrospective cohort study published in September 2021 in Ontario, Canada, proves the correlation between long-term catheterization and bladder cancer incidence and mortality. In that study, thirty-six thousand nine hundred three patients with long-term catheterization were compared to one hundred ten thousand seven hundred nine patients without a history of catheterization using HealthCanada records. Patients in the catheter group develop bladder cancer four times more often than the noncatheter group. Bladder cancer-specific death was more than eight times higher among the patients who were long-term catheter users than the noncatheter group.

11. Cancer is the third leading cause of death in individuals with spinal cord injury or disorder (SCI/D), and bladder cancer is the second most common cancer type in these individuals.

12. Urinary bladder cancer in SCI/D patients differs considerably from urinary bladder cancer in able-bodied patients. SCI/D patients show a significantly higher proportion of the more aggressive squamous cell carcinoma than that of the general population. Consequently, the survival rate is extremely unfavorable.

13. Exposure to phthalates including DEHP, butyl benzyl phthalate (BBzP), and Diisobutyl phthalate (DiBP) has been positively associated with prostate cancer in men.

14. Human and rodent data suggest that DEHP induces cancer through multiple molecular signals, including DNA damage.

15. The European Union has determined that DEHP is a reproductive toxicant and endocrine disruptor, and in 2017 adopted regulations requiring a benefit-risk assessment before

certain phthalates, including DEHP, can be used in medical devices.

16. The state of California has determined that DEHP is a reproductive and developmental toxicant and a carcinogen, and advises patients to request devices that do not contain DEHP when undergoing medical treatment.

17. In 2002, based on the FDA's 2001 safety assessment, the FDA recommended that health care providers consider alternatives to DEHP when conducting procedures on high-risk patients.

18. The American medical association passed an organizational resolution for members encouraging alternatives to DEHP products.

19. The American public health association issued a policy statement discouraging the use of DEHP and other phthalates in facilities that serve vulnerable populations.

20. American patients receiving care in hospitals and other settings are overexposed to dangerous levels of phthalates. This critical patient safety issue has been the subject of extensive research over the last few decades, but thus far the guidance to protect patients from these harmful chemicals has done very little to actually reduce the use of these chemicals in health care settings.

21. Despite these findings and the growing body of evidence that has confirmed earlier research and identified additional risks of adverse health effects on vulnerable patients, there has been minimal progress in the United States over the last twenty years in reducing the use of DEHP in medical devices.

22. Since 2018, the office of inspector general of the United States department of health and human services has recommended a significant reduction in reimbursement amounts by the centers for Medicare and Medicaid services of the United States department of health and human services (CMS) for intermittent catheters as the Medicare and Medicaid programs have paid substantially more than commercial payors for

intermittent urinary catheters.

23. Each of the three billing categories of intermittent catheters, straight tip, curved tip, and sterile kit, show large differences between Medicare payments and acquisition costs, which indicates a potential for substantial savings both to the Medicare program and Medicare beneficiaries who share responsibility for payment of the Medicare-allowed reimbursement amount.

24. Nearly twenty years after the FDA's first guidance was issued on phthalates, the time has finally come to take aggressive and necessary steps forward to protect the lives of Iowa Medicaid patients.

25. At the very least, the Iowa Medicaid program should not reimburse medical device manufacturers, distributors, or suppliers for catheters that are made with the known carcinogen DEHP.

Sec. 3. REVIEW OF CATHETERS —— REIMBURSEMENT SUSPENSION PENDING COMPLETION OF REVIEW —— MEDICAID PROGRAM.

1. The Medicaid program shall not reimburse claims for catheters made with Di(2-ethylhexyl)phthalate (DEHP) until after the completion and pending the results of the review under this section that includes the Medicaid director's recommendation regarding which catheters should be reimbursable under the Medicaid program.

2. Pending completion of the review under this section, all of the following shall also apply:

a. Notwithstanding any provision of law to the contrary, the use of catheters made with DEHP is deemed unsafe for Iowa Medicaid recipients.

b. Any rules previously adopted prescribing the conditions under which any catheter made with DEHP may be safely used are void, and shall have no force or effect.

c. The Medicaid director shall object to any notification of an intended use of catheters made with DEHP and shall not adopt rules prescribing any conditions under which any catheter made

with DEHP may be safely used as an invasive medical device.

d. In establishing the safety of alternatives to catheters made with DEHP that may be used and reimbursed under the Iowa Medicaid program, the Medicaid director shall consider, in addition to criteria under section 409 of the federal Food, Drug, and Cosmetic Act, 21 U.S.C. §348, potential adverse effects of exposure to an alternative substance on vulnerable populations, including pregnant women, infants, children, persons with disabilities, the elderly, and populations with high exposure, including workers who are exposed through production practices or clinical handling of the final product.

e. The Medicaid director shall inform Medicaid providers and recipients of the prohibition against reimbursement of catheters made with DEHP during the pendency of the review and shall make available to Medicaid providers and recipients a list of alternative products that are not made with DEHP and that are reimbursable under Medicaid when provided to Medicaid recipients during the pendency of the review.

3. The Medicaid director shall cause a review to be conducted by the university of Iowa public policy center or other appropriate state entity that includes all of the following:

a. A historical records review of Medicaid recipients who used catheters made with phthalate chemicals like DEHP which are subject to regulation by the United States food and drug administration to determine whether Iowa Medicaid recipients who use these medical devices made with phthalate chemicals have a higher incidence rate of bladder cancer than the general population.

b. Identification of the brands of catheters with DEHP that are correlated with higher levels of bladder cancer in the Iowa Medicaid population of catheter users by comparing the diagnosis codes associated with bladder cancer against individual patient-level data that includes catheter billing at the stock keeping unit level to determine the DEHP

concentration of these devices.

c. A comparison of the average lifetime cost of care for a Medicaid recipient who uses catheters with the average lifetime cost of care of a Medicaid recipient who has bladder cancer treatment.

d. Consideration of the disproportionate exposure of invasive medical devices containing phthalate chemicals on members of communities of color and with disabilities, and the health effects of such exposure on members of such communities, including any increased risk of cancer, endocrine disruption, effects on reproductive health, and other risks to human health.

4. No later than July 1, 2025, the Medicaid director shall issue a report on the findings of the review, submit the report to the governor and the general assembly, and post the report on the department of health and human services internet site. The report shall include the Medicaid director's recommendation as to which catheters should be reimbursed under the Medicaid program, including specifically whether catheters made with DEHP should be reimbursed under the Medicaid program.

5. For the purposes of this section, catheters include intermittent and indwelling catheters.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to the use and reimbursement of certain catheters under the Medicaid program.

The bill shall be known as the "Better Caths for Iowa Act".

The bill includes findings relating to the use of phthalates, a family of toxic endocrine-disrupting chemicals that include Di(2-ethylhexyl)phthalate or DEHP, that when added to certain plastic products increase their flexibility. These products include catheters. The findings include that American patients receiving care in hospitals and other settings are overexposed to dangerous levels of phthalates;

exposure to phthalates can do lasting harm to child brain development and increases children's risks for learning, attention, and behavior disorders; a pregnant woman's exposure to phthalates can harm reproductive tract development in male babies which may have lifelong consequences; phthalates have been banned from use in children's toys in the United States; women have higher exposure to phthalates found in care products than men; African American and Latina women have higher exposure to certain phthalates compared with white women; persons with disabilities who use catheters experience bladder cancer at four times the national average; little has been done to protect patients from these harmful chemicals to actually reduce the use of these chemicals in health care settings; that the three billing categories of intermittent catheters, straight tip, curved tip, and sterile kit, show large differences between Medicare payments and acquisition costs, indicating the potential for substantial savings both to the Medicare program and Medicare beneficiaries who share responsibility for payment of the Medicare-allowed reimbursement amount; and that at the very least, the Iowa Medicaid program should not reimburse medical device manufacturers, distributors, or suppliers for catheters that are made with the known carcinogen DEHP.

The bill provides the Medicaid program shall not reimburse claims for catheters made with DEHP, until after the completion and the results of the review required under the bill including the recommendation of the Medicaid director regarding reimbursement of catheters under the Medicaid program.

Pending completion of the review under the bill, the use of catheters made with DEHP is deemed unsafe for Iowa Medicaid recipients; any rules previously adopted prescribing the conditions under which any catheter made with DEHP may be safely used are void, and shall have no force or effect; the Medicaid director shall object to any notification of an intended use of catheters made with DEHP and shall not adopt

rules prescribing any conditions under which any catheter made with DEHP may be safely used as an invasive medical device; and in establishing the safety of alternatives to catheters made with DEHP that may be used and reimbursed under the Iowa Medicaid program, the Medicaid director shall consider, in addition to criteria provided under federal law, the potential adverse effects of exposure to an alternative substance on vulnerable populations, including pregnant women, infants, children, persons with disabilities, the elderly, and populations with high exposure, including workers who are exposed through production practices or clinical handling of the final product. The Medicaid director is required to inform Medicaid providers and recipients of the prohibition against reimbursement of catheters made with DEHP during the pendency of the review and make available to Medicaid recipients and providers a list of alternative products that are not made with DEHP and that are reimbursable under Medicaid when provided to Medicaid recipients during the pendency of the review.

The Medicaid director shall cause a review to be conducted of catheters, including a historical records review of Medicaid recipients who used catheters made with phthalate chemicals including DEHP, to determine whether Iowa Medicaid recipients who use these medical devices have a higher incidence rate of bladder cancer than the general population; identification of the brands of catheters with DEHP that are correlated with higher levels of bladder cancer in the Iowa Medicaid population of catheter users; a comparison of the average lifetime cost of care for a Medicaid recipient who uses catheters with the average lifetime cost of care for a Medicaid recipient who has bladder cancer treatment; consideration of the disproportionate exposure of invasive medical devices containing phthalate chemicals on members of communities of color and with disabilities, and the health effects of such exposure on members of such communities, including any increased risk of cancer, endocrine disruption, effects on reproductive health,

and other risks to human health. No later than July 1, 2025, the Medicaid director shall issue a report on the findings of the review, submit the report to the governor and the general assembly, and post the report on the department of health and human services internet site. The report shall include a recommendation as to whether catheters made with DEHP should be reimbursed under the Medicaid program.

Under the bill, catheters include intermittent and indwelling catheters.