Impact of ACIP Changes on Vaccine Injury Compensation Programs

Overview: This document analyzes how changes in ACIP recommendations may impact federal vaccine injury compensation programs for flu and COVID-19 vaccines, and RSV immunizations, focusing on coverage, liability protections and regulatory processes. This document will be updated regularly, as reflected in the header.

Summary of Impact: Changes to ACIP recommendations with respect to flu vaccines, COVID-19 vaccines, or RSV immunizations would have limited impacts on federal programs that limit provider or manufacturer liability. Flu vaccines are covered under both the National Vaccine Injury Compensation Program ("**VICP**") and the Countermeasures Injury Compensation Program ("**CICP**"). COVID-19 vaccines are covered only under the CICP, and RSV is not covered under either program. Changes to ACIP recommendations would not affect the VICP. With respect to CICP, changes to ACIP recommendations affect whether pharmacy personnel and certain students receive immunity protections. However, the Secretary of HHS could take other actions to modify the programs.

- **VICP:** VICP covers injuries from seasonal influenza vaccines. (42 CFR 100.3; see also HRSA FAQ). VICP does not currently cover RSV immunizations or COVID-19 vaccines.
    a. Pursuant to the National Childhood Vaccine Injury Act of 1986, individuals may not file civil claims greater than $1000 against the "administrator" or "manufacturer" of a covered vaccine for vaccine-related injury or death until after the VICP program mechanism has been exhausted. There is no definition for "administrator" in the statute, regulations, or guidance, but at least one court has determined that the term refers to the person who actually inoculates the individual, and not a referring provider. (*Klahn v. Secretary of Dept. of Health and Human Services*, 31 Fed. Cl. 382, 389 (1994)). Individuals who accept the damages awarded through the VICP process are barred from filing a civil claim for the same injury, although individuals who reject the awarded damages are not so barred. The statute also generally bars civil claims against manufacturers for "unavoidable adverse side effects."
    b. The initial Vaccine Injury Table was set forth in the National Childhood Vaccine Injury Act of 1986, as amended (42 USC § 300aa-10, et seq.). The statute provides for the administrative revision of the table by the Secretary of HHS via a rulemaking proceeding, with such changes applying only to petitions filed after the effective date of the regulation. (USC § 300aa–14(c)). However, vaccines are not considered "covered vaccines" for purposes of VICP unless they are also subject to the excise tax imposed under 26 U.S.C. § 4131. Thus, the effective inclusion of a new vaccine requires both regulatory action by HHS and congressional action to impose or maintain the tax, which is administered by the Department of the Treasury. (42 C.F.R. § 100.3(e)(8)) Influenza vaccines were not included in the initial table but were included by a subsequent rulemaking. (42 CFR 100.3(e)(6)).

c. ACIP recommendations are relevant to the process for adding *new* vaccines to the table (when CDC recommends a new vaccine for routine administration to children or pregnant women, the Secretary is directed to add it to the table within two years of such recommendation). (USC § 300aa–14(e)). New vaccines will be included in the Table "as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the Federal Register to announce the effective date of such a tax". (42 CFR 100.3(e)(8)).
d. However, the statute does not provide a clear mechanism to remove vaccines from the table. The provisions permitting the Secretary to modify the table via a rulemaking state that such modifications "may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death." (USC § 300aa–14(c)). This notably does not permit the Secretary to actually remove a category of vaccines from the table. Moreover, even if the Secretary were to remove a vaccine from the Table via rulemaking, the vaccine would continue to be covered by VICP unless and until Congress repeals or amends the underlying excise tax imposed.
e. We identified one instance in which the Secretary amended the table to remove a category of vaccines from the table. (United States, Department of Health and Human Services. "National Vaccine Injury Compensation Program: Removal of Separate Category for Vaccines Containing Live, Oral, Rhesus-Based Rotavirus From the Vaccine Injury Table." 73 Fed. Reg. 59515 (Oct. 9, 2008)). This was adopted without standard notice and comment procedures as the amendment was "technical in nature…no persons have claims that could be pursued under the category that is being removed from the Table through this interim final rule" due to fact-specific circumstances.

- In sum, even if ACIP downgrades or rescinds its recommendations for flu vaccines, the Vaccine Injury Table remains unchanged in the absence of further action by the Secretary and Congress.

- **CICP:** Injuries from COVID-19 vaccines are covered through the CICP. (42 USC §§ 247d-6d, 247d-6e). They are "covered measures" pursuant to the PREP Act Declaration for COVID-19, as amended (the "**Declaration**"). In 2021, the Declaration was amended to also cover the administration of flu vaccines. (HHS COVID-19 PREP Act Extension).
    - The CICP provides that covered persons "shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual" of a covered countermeasure as set forth in a Declaration, such as the COVID-19 and flu vaccines, except in the case of willful misconduct by the covered person. The immunity applies to any claim that has a causal relationship with the use or

administration of the covered countermeasure by a covered person, "including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." Covered persons include the United States, manufacturers, distributors, program planners, qualified person who prescribed/administered/dispensed the countermeasure, or an official, agent, or employee of the foregoing. (42 USC §247d-6d). The CICP also includes a compensation program for people injured by covered countermeasures.

f. Under the statute, a "qualified person" includes licensed health professionals or other individuals who are authorized to prescribe, administer, or dispense the countermeasures in the applicable state; or any other category of person identified by the Secretary in the Declaration. The Declaration goes into significant detail on the other categories of persons that are authorized to administer covered countermeasures (including pharmacy personnel; any member of a uniformed service; federal government employees, contractors or volunteers; midwives; paramedics and EMTs; physician assistants; respiratory therapists; dentists; podiatrists; optometrists; veterinarians; and students of the foregoing professions) and the conditions under which they are permitted to administer them.

- COVID-19 and flu vaccines are eligible for the CICP as long as the Declaration remains in effect or until the Declaration is amended to remove such vaccines from coverage. The Declaration is currently set to expire as of December 31, 2029 (HHS COVID-19 PREP Act Extension).

- The Secretary of HHS may amend any portion of the Declaration with respect to a covered countermeasure, though such an amendment cannot retroactively limit claims. (42 USC 247d-6d(b)(4)).

- ACIP recommendations are relevant to determine whether pharmacy personnel and certain additional healthcare professionals and students[1] are "qualified persons" entitled to liability protection for vaccine administration. Such personnel are covered only if the vaccine is ordered and administered according to CDC/ACIP recommendations (Covid) or CDC/ACIP's standard immunization schedule (flu). The same applies to students administering Covid vaccines pursuant to a school or training program. (HHS COVID-19 PREP Act Extension).

    i. The Declaration explicitly preempts any state law that would otherwise prohibit licensed pharmacists, pharmacy interns, and qualified pharmacy technicians from prescribing, dispensing, or administering covered countermeasures. (HHS COVID-19 PREP Act Extension).

[1] The Declaration authorizes certain other healthcare professionals whose scope of practice may not ordinarily include vaccination (e.g., EMTs) certain healthcare professionals whose license has lapsed in the last five years, and certain healthcare professional students to administer Covid and flu vaccines, only to the extent consistent with CDC schedules.

About the Common Health Coalition (CHC)

Founded in 2023, the Common Health Coalition (CHC) brings together leading health organizations in pursuit of a reimagined health system, one in which the nation's healthcare and public health systems no longer work in parallel, but hand in hand, with better health for all as the common goal. The Coalition encompasses 300+ members across the country. CHC is working with providers, payers, public health agencies, and other key actors to develop and implement a coordinated strategy for the continued coverage, access, and uptake of COVID-19 and flu vaccines and RSV immunizations. Focusing on the fall respiratory season, CHC is building consensus on industry best practices for vaccine access, analyzing and navigating the evolving coverage and regulatory landscape, and developing tools that promote a shared understanding of key issues and impacts across all stakeholders.

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