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Fraud, Waste and Abuse: Illegal Billing & Overpayments Under the Vaccines for Children Program

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In this article, the authors review the eligibility requirements for the Vaccines for Children (VFC) program and discuss proper billing guidelines established by the federal and state VFC programs and avenues available for recovering overpayments would prove beneficial for VFC providers and insurers.

In the late 1980s and early 1990s, a measles epidemic swept through the United States, resulting in hundreds of deaths. The disease spread rapidly among children, in particular. A surplus of measles vaccinations was available in the United States, which may have significantly curbed the impact of the epidemic. While supply was not an issue, the inability of American families to afford vaccines for their children played a major role in the outbreak.

In response, Congress passed the Omnibus Budget Reconciliation Act, creating the federal Vaccines for Children (VFC) program. The VFC program provides certain vaccinations to children at no cost.¹ The goal of the program is to remove the cost barrier preventing parents from ensuring their children are vaccinated and to decrease the risk of future outbreaks.

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Providers authorized under the VFC program are prohibited from billing patients or insurers for the cost of the vaccines themselves, since they are provided by the government free of charge. Despite this prohibition, there are several instances of providers, perhaps inadvertently, charging patients' insurers for the cost of vaccines and of insurers mistakenly paying these charges. Insurers often discover the mistake well after making payments and attempt to recover their overpayments from the provider. Such discoveries signal that a thorough review of program eligibility requirements, proper billing guidelines established by the federal and state VFC programs, and avenues available for recovering overpayments would prove beneficial for VFC providers and insurers. The following sets out to deliver just that.

THE VACCINES FOR CHILDREN PROGRAM: ELIGIBILITY

Under the VFC program, all children in the U.S. who are 18-years-old and younger are entitled to free vaccinations provided for by the program if they are:

- (1) Eligible for Medicaid;
- (2) Enrolled in CHIP;
- (3) Uninsured;
- (4) Underinsured; or
- (5) American Indian or an Alaskan Native.²

Children who are insured and whose insurance covers the costs of vaccinations are not eligible for the VFC program.³ Currently, the VFC program provides vaccinations for Diphtheria, Haemophilus influenzae type b, Hepatitis A, Hepatitis B, Human Papillomavirus, Influenza, Measles, Meningococcal disease, Mumps, Pertussis, Pneumococcal disease, Polio, Rotavirus, Rubella, Tetanus, and Varicella.⁴

The federal government funds the VFC program and provides the funding to the Center for Disease Control (CDC).⁵ The CDC, in turn, purchases discounted vaccines and distributes the vaccines to health-care providers participating in the program.⁶ Each state has its own VFC program through which state-based healthcare providers register to administer VFC vaccines to children.⁷ Each state also has a VFC

provider manual establishing the requirements and restrictions applicable to VFC providers.

REIMBURSEMENT UNDER THE VFC PROGRAM

Reimbursement of providers through the VFC program is established by federal law. Each state's provider manual mirrors the federal statutory payment provisions. 42 C.F.R. § 441.615, the federal statute establishing the VFC payment requirements, separates charges for the administration of the vaccine (the provider's labor) from charges for the vaccine itself.⁸ Providers are also entitled to reimbursement for the service of administering VFC vaccines.⁹ The HHS Secretary publishes maximum charges VFC providers may charge for administration.¹⁰ Maximum charges vary on a region-by-region basis.¹¹ Providers are prohibited from denying a patient a VFC vaccine because of the patient's inability to pay the administration charge.¹²

Reimbursement for the vaccines themselves, on the other hand, are prohibited by the VFC program.¹³ This prohibition restricts providers from charging patients or insurers for the costs of vaccines. Some state provider manuals require providers to submit a bill for \$0.00 to ensure a record is kept of vaccines provided under the VFC program.¹⁴

THE ILLEGAL BILLING AND OVERPAYMENT PROBLEM

Because providers are prohibited from charging for vaccines, providers should not bill insurers of VFC-qualifying children for vaccines and insurers should not pay any submitted bills for vaccines. Despite this prohibition, providers have billed insurers for VFC vaccines and, problematically, insurers have paid providers for these vaccines. This scenario creates an illegal billing and overpayment problem.

Providers may bill for VFC vaccines for a variety of reasons, but the most likely is the result of a lack of diligence or mistake. Because only certain minor-patients are eligible to receive free vaccines under the VFC program, providers must perform due diligence to ensure minor-patients are properly screened to determine whether patients are entitled to free vaccines. Lack of diligence or mistakes regarding patients' VFC status can result in illegal billing of VFC vaccines to eligible minors.

Similarly, insurers may mistakenly pay improperly billed VFC vaccines due to the same lack of diligence in determining whether minor-patients are VFC-eligible. Insurers often only realize the overpayments have been made months or years after the fact during internal audits. This can result in significant losses for the insurer when dealing with larger healthcare providers which submit voluminous claims for

payment, such as hospitals. Providers may be unwilling or unable to repay large amounts improperly received months or years after the fact. The issue then arises whether insurers can recoup the overpaid amounts.

FRAUD, WASTE AND ABUSE

The VFC federal statutes and state provider manuals do not establish a mechanism for an insurer to recover mistaken overpayments on illegally billed VFC claims. Because of this, insurers must resort to common law remedies, such as recoupment, account stated, or unjust enrichment. If a provider is in-network with the overpaying insurer, the insurer's contract with the provider may also provide a mechanism for relief. While the provider manuals may not provide a direct avenue for relief, they do include language beneficial to efforts to recoup improper VFC claim payments and every VFC provider must sign and agree to the terms of their applicable VFC provider manual.

Every state provider manual has a designated section pertaining to reimbursement for VFC vaccines and administration.¹⁵ These sections include the prohibition on billing insurers of VFC-eligible recipients for the VFC vaccines themselves.¹⁶ Importantly, each state provider manual also includes the defined terms "fraud" and "abuse."¹⁷ The manuals adopt the Medicaid regulatory definitions of these terms and define them as follows:

Fraud means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable Federal or State law.¹⁸

Abuse means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes beneficiary practices that result in unnecessary cost to the Medicaid program.¹⁹

Some states also include the term "waste" in their manuals and define waste as including any conduct that may cause unnecessary costs to the VFC program.²⁰ Other states limit the term "waste" to conduct resulting in the destruction, loss, or expiration of vaccines.²¹

While these definitions may leave some question as to whether or not unintentionally billing for VFC vaccines constitutes fraud, waste, or abuse, the state VFC provider manuals largely remove any doubt. Many (though not all)²² of the state provider manuals include specific examples of provider conduct that constitutes fraud, waste, and abuse.

States generally include billing for VFC vaccines in their examples of fraud, waste, and abuse. For example, the California provider manual states outright: “[b]illing for the cost of vaccines is prohibited by federal law, and billing constitutes fraud or abuse and might lead to termination from the VFC Program.”²³ The Texas provider manual explains that fraudulent or abusive practices include: “[b]ill[ing] a patient or third party for TVFC vaccine (other than administration fees).”²⁴ Massachusetts, Michigan, New York and Pennsylvania also include billing insurers for VFC vaccines as an example of a fraudulent or abusive activity.²⁵ Billing insurers is also included as fraud and abuse in the VFC Operations Guide published by the CDC, which serves as a model that states may choose to follow in their VFC programs.²⁶ Insurers seeking reimbursement in states that include improper billing in their examples of fraud and abuse can cite the applicable provider manual in support of their claim that the provider is in violation of the VFC program.

In addition to common law claims supported by VFC provider manual terms, insurers have another powerful tool to aid in recovering VFC overpayments. Because the VFC program often provides vaccines to Medicaid recipients, billing for the vaccines may violate the applicable state Medicaid program. Providers may face loss of their Medicaid licensure if they are found to have illegally billed for VFC vaccines.

Providers may assert various defenses to recoupment efforts by insurers. In particular, claims falling outside of the applicable statute of limitations for the causes of action raised by insurers would be barred. Other defenses, such as waiver or mutual mistake may be effective, but the lack of caselaw on this issue (VFC overpayment claims are generally resolved pre-suit or through binding arbitration) makes it difficult to assess viable defenses.

CONCLUSION

VFC overpayment claims can result in heavy losses for insurers, significant risk for providers, and frustration of the goals of the VFC program to provide vaccines at no cost. An increased understanding of the VFC program and the strengths and weaknesses of recovering on VFC overpayment claims can help insurers and providers avoid the overpayment problem.

On the providers' end, avoiding billing for VFC vaccines through proper screening of VFC eligibility and flagging improper charges can avoid the overpayment issue.

On the insurers' end, implementing procedures to detect VFC-eligible claims and bills for the costs of vaccines (as opposed to vaccine administration), can direct the insurers to deny VFC vaccine claims instead of paying them, which would also avoid the overpayment issue. With multiple opportunities for both sides to avoid this problem, VFC overpayment seems to result from a lack of awareness and/or diligence. Let this serve as a first step in remedying the former, in an aim to aid the latter.

NOTES

1. 42 CFR § 441.600.
2. 42 CFR § 441.605.
3. *Id.* at (a)(2)-(3).
4. CDC, About the Vaccines for Children (VFC) Program, (June 26, 2024), available at <https://www.cdc.gov/vaccines-for-children/about/index.html>.
5. *Id.*
6. *Id.*
7. *Id.*
8. 42 CFR § 441.615.
9. *Id.* at (a)(1).
10. *Id.* at (b).
11. *Id.* at (c).
12. *Id.* at (a)(2).
13. *Id.* at (a).
14. See e.g., Michigan Vaccines for Children (VFC) Provider Manual, p. 20 (Nov. 7, 2023), available at https://www.michigan.gov/-/media/Project/Websites/mdhhs/Folder2/Folder95/Folder1/Folder195/Michigan_VFC_Provider_Manual.pdf?rev=da49a8951e5548d591e8dfb0921aab02.
15. See e.g., California Vaccines for Children Program Provider Operations Manual, pp. 22-24 (2019), available at <https://eziz.org/assets/docs/IMM-1248.pdf>; Florida Vaccines for Children (VFC) Program Policy Handbook, pp. 53-58 (2020), available at [2020-vfc-provider-handbook.pdf](https://www.floridahealth.gov/2020-vfc-provider-handbook.pdf) (floridahealth.gov); Massachusetts 2024 Guidelines for Compliance with Federal and State Vaccine Administration Requirements, Sec. A-5, p. 3, available at <https://www.mass.gov/doc/guidelines-for-compliance-with-federal-vaccine-administration-requirements-2024/download>; Michigan Provider Manual, Sec. 8, pp. 71-74; NYC DOHMH Bureau of Immunization VFC Policy on Fraud and Abuse, Sec. (3)(a), p. 3 (Apr. 13, 2010), available at <https://www.nyc.gov/assets/>

doh/downloads/pdf/imm/vfc-fraud-abuse-policy.pdf; Pennsylvania Immunization Program: Fraud and Abuse, p. 1 (Jan. 2024), available at <https://www.pa.gov/content/dam/copapwp-pagov/en/health/documents/topics/documents/programs/immunizations/2.%20Fraud%20and%20Abuse.pdf>; Texas Vaccines for Children and Adult Safety Net Provider Manual, Ch. 6, pp. 105-106 (2024), available at https://www.dshs.texas.gov/sites/default/files/LIDS-Immunizations/pdf/pdf_stock/11-13602.pdf.

16. See e.g., California Provider Manual, p. 22; Florida Provider Manual, p. 55; Massachusetts Provider Manual, Sec. A-5, p. 3; Michigan Provider Manual, Sec. 8, p. 72; New York Provider Manual, p. 3; Pennsylvania Provider Manual, p. 1; Texas Provider Manual, Ch. 6, p. 104.

17. See e.g., California Provider Manual, p. 7; Florida Provider Manual, p. 54; Massachusetts Provider Manual, Sec. A-5, p. 3; Michigan Provider Manual, Sec. 8, p. 72; New York Provider Manual, p. 2; Pennsylvania Provider Manual, p. 1; Texas Provider Manual, Ch. 6, p. 103.

18. 42 CFR § 445.2.

19. Id.

20. See e.g., Texas Provider Manual, Ch. 6, p. 104 (defining waste as “[t]he careless, inefficient, or unnecessary use of TVFC program resources.”).

21. See e.g., Florida Provider Manual, p. 55.

22. Florida is an example of one state that does not provide examples of conduct constituting fraud and abuse in its VFC provider manual.

23. California Provider Manual, p. 22.

24. Texas Provider Manual, Ch. 6, p. 104.

25. Massachusetts Provider Manual, Sec. A-5, p. 3; Michigan Provider Manual, Sec. 8, p. 72; New York Provider Manual, Sec. (3)(a), p. 3; Pennsylvania Provider Manual, p. 1.

26. CDC, VFC Operations Guide Module 5, p. 68 (last updated July 1, 2024), available at https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/vfc-ops-guide_version-4.0_july-2024_low-res-508-rev-2.pdf.

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