Strategies to Address Policy Barriers to Adult Immunizations in Federally Qualified Health Centers

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EXECUTIVE SUMMARY

This white paper outlines policy barriers and strategies that specifically impact Federally Qualified Health Centers (FQHCs) in their efforts to increase adult immunization rates among their medically underserved patients. While FQHCs encounter many barriers that also impact other providers (e.g., issues with storage, inventory management, and immunization information systems) this paper focuses specifically on challenges and opportunities that are based in policy, and that are unique (or largely unique) to FQHCs.

The white paper addresses six areas of FQHC policy, and provides background information and potential strategies to increase adult immunization rates for each.

Statutory & HRSA Requirements for FQHCs

To qualify as an FQHC, an organization must adhere to the requirements laid out in Section 330 of the Public Health Service Act. These include requirements to provide vaccines to all patients (both children and adults) regardless of ability to pay, and to report data as requested. The federal Health Resources and Services Administration (HRSA) administers the Section 330 program, ensuring FQHCs' compliance with all requirements and overseeing data collection.

The following strategies related to federal requirements on FQHCs may help increase adult immunization rates among FQHCs:

1. ***HRSA could add a composite adult immunization measure to its annual reporting requirements for FQHCs.*** While FQHCs submit data to HRSA annually on three immunizations measures, none of these measures are specific to adults, and there are concerns that the reported data understates FQHCs' actual immunization activities. Adding a composite measure of adult immunization could help increase FQHCs' attention to this topic.
2. ***HRSA could consider performance on an adult immunization measure when determining which FQHCs receive supplemental grant funding and/or public recognition.*** HRSA provides public recognition and supplemental grant funding to FQHCs who perform well on specific clinical quality measures. At present, childhood immunization rates are considered when these awards are made, but adult immunization rates are not. By basing future awards in whole or in part on adult immunization rates, HRSA could further incentivize FQHCs to focus on this issue.
3. ***Outside groups could incentivize FQHCs to focus on adult immunization by offering funding and/or public recognition linked to adult immunization rates***. It would take several years for HRSA to adjust its reporting requirements and awards to focus on adult immunization. In the meantime, other organizations could incentivize FQHCs to focus on this area by offering funding and/or public recognition based on their performance in this area
4. ***Outreach and support could target to FQHCs that focus on specific at-risk populations.*** To address specific at-risk populations, efforts could target the 9% of FQHCs that focus on serving migrant and seasonal farmworkers, and/or the 9% that focus on persons experiencing homelessness.

FTCA: Federally-Supported Medical Malpractice Insurance for FQHCs

FQHCs that receive HRSA grant funding also receive free medical malpractice insurance through the Federal Tort Claims Act (FTCA). The following strategies related to FTCA may increase adult immunization rates among FQHCs:

1. ***Educate FQHCs that FTCA coverage applies to community-based immunization events, such as immunization fairs.*** FTCA coverage is generally limited to services provided to patients who are seen at official FQHC locations. Educating FQHCs that FTCA covers community-based activities such as immunization fairs may encourage FQHCs to engage in these activities.
2. ***FQHCs could recruit volunteer clinicians to assist with immunization efforts, highlighting the availability of free malpractice coverage.*** FTCA coverage can be extended to health professionals who volunteer at FQHCs. This can be an effective incentive for recruiting clinicians to volunteer with FQHCs, as it removes one of the major barriers clinicians express about volunteering. Volunteer clinicians can be encouraged to participate in community-based immunization events, and also to serve as the "immunization champion" within a FQHC.

Medicaid

Medicaid is the largest source of insurance for FQHC patients, covering almost half of FQHC patients nationwide. Among the individuals and organizations interviewed for this report, the most frequently reported barrier to increasing adult immunization rates among Medicaid patients by FQHCs was the "lack of Medicaid reimbursement." Technically, Medicaid does pay FQHCs for vaccines, as it includes a small amount of reimbursement towards these costs every time it provides a per-visit payment under the Prospective

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Payment System (PPS). However, since immunization-only visits with providers such as nurses and pharmacists generally do not result in a PPS per-visit payment, FQHC staff often do not recognize that they are being reimbursed for these costs.

Many respondents suggested that having state Medicaid programs reimburse FQHCs separately for immunization-only visits with nurses or pharmacists would remove this barrier and help raise adult immunization rates at FQHCs. While this is technically possible, it would likely be a heavy lift in many states, as making the required changes could often impose substantial administrative, policy, and financial impacts on the state Medicaid agency for reasons unrelated to adult immunization. This is because allowing for nurse/pharmacist-only immunization visits to be separately billable would require recalculating all FQHCs' PPS rates, which in turn could require the state to:

- establish or update administrative systems to collect and analyze each FQHC's costs;
- address requests from many other groups (beyond the adult immunization community) to make specific changes to the PPS structure; and
- increase rates to more accurately reflect current costs.

To determine the effort involved in recalculating FQHC PPS rates in a specific state, individuals are strongly encouraged to contact the state association of FQHCs, often called the Primary Care Association (PCA).

Medicare

Medicare's reimbursement rules for adult vaccination are different for FQHCs than for most other outpatient providers. For most non-FQHCs, Medicare Part B reimburses for influenza, pneumococcal, and hepatitis B vaccines, and Part D reimburses for all other covered vaccines. In contrast, FQHCs may not bill for any vaccines under Part D, or under standard Part B processes. Instead, for FQHCs:

- influenza and pneumococcal vaccines are reimbursed via an annual cost report, which results in payment being delayed up to 18 months after the date of vaccine administration
- other vaccines are folded into PPS reimbursement rates. Similar to the Medicaid PPS, Medicare FQHC PPS payments are only provided for face-to-face visits with specific types of providers.

These parameters suggest the following strategies:

1. ***FQHCs could maximize nurse/pharmacist visits for influenza and pneumococcal vaccines for Medicare patients.*** Since reimbursement for influenza and pneumococcal vaccines is made outside of the Medicare PPS, FQHCs are reimbursed separately and explicitly for administering these vaccines – even when they are provided by a nurse or pharmacist.
2. ***To reduce the delays in reimbursement for influenza and pneumococcal vaccines, CMS could permit FQHCs to bill for these vaccines under the Part B fee schedule at the time of service, as long as these interim payments are later reconciled with their cost reports.*** At present, there are substantial delays (up to 18 months from the time of vaccine administration) for FQHCs to receive reimbursement for influenza and pneumococcal vaccines. CMS could lessen the impact of these delays by permitting FQHCs to receive interim reimbursement for these services under the Part B fee schedule, and then reconciling these interim payments to actual costs during the cost reporting process.
3. ***FQHCs can leverage Medicare visits for Diabetes Self-Management Therapy (DSMT) and Medical Nutrition Therapy (MNT) to address vaccination.*** Visits with DSMT and MNT providers are separately "billable" under the FQHC Medicare PPS, meaning that they trigger a per-visit PPS payment. While DSMT and MNT providers are rarely eligible to administer vaccines themselves, they can use their interactions with patients to increase adult immunization rates, either by encouraging patients to get vaccinated, or having qualified providers administer vaccinations in conjunction with these visits.

Pharmacy

To increase adult immunization rates among their patients and broader community, FQHCs with in-house pharmacies could expand pharmacists' role in recommending and administering adult vaccines. Consistent with state law, pharmacists could focus on increasing adult immunization rates in the FQHC clinical setting, in the pharmacy, and at community-focused events such as immunization fairs.

340B

The 340B Drug Discount Program does not require manufacturers to offer discounts on vaccines. Nonetheless, FQHCs may be able to access significant discounts on vaccines purchased through the 340B HRSA-designated Prime Vendor, Apexus.

Veterans

Health centers can reach out to veterans who normally receive their care through Veteran Affairs (VA) providers to offer them influenza vaccines. Health centers that have a contract with the VA will be reimbursed at prevailing Medicare rates for this service, and the veteran will not be charged a copay.

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INTRODUCTION

This white paper outlines policy barriers and strategies that specifically impact Federally Qualified Health Centers (FQHCs) in their efforts to increase adult immunizations rates among their medically underserved patients.

In researching this white paper, we spoke with clinical, pharmacy, and administrative staff from FQHCs; state associations of FQHCs (called Primary Care Associations, or PCAs); staff of two policy-focused organizations whose work includes immunizations; staff from state and local health departments; and policy staff from the U.S. Department of Health and Human Services, including the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA). We also reviewed relevant policy documents, and incorporated qualitative information surrounding FQHC practices around adult immunization gleaned from conversations. The guiding principles for the work surrounding adult immunizations was based on the Standards for Adult Immunization Practice by the National Vaccine Advisory Committee (NVAC).[1]

Our research identified a wide range of barriers and opportunities that impact FQHCs' ability to meet Standards for Adult Immunization Practice. Many of these are specific to FQHCs, as they involve programmatic, policy and/or reimbursement rules that generally apply only to them. However, we also identified several barriers and opportunities that impact not only FQHCs, but many other types of providers who seek to increase adult immunization rates. While this white paper focuses on issues that are specific to FQHCs, please note that FQHCs also encounter the following issues that are shared among many provider types:

BARRIERS:

- Immunization information systems – including lack of availability, lack of bi-directional interface capabilities, lack of real-time data access, and lack of registry access across state lines
- Physical storage of vaccines – such as the need for space, proper equipment, ongoing monitoring of temperature, and the associated costs
- Inventory management of vaccines - staff time, burden, and cost of vaccine inventory and potential wastage of short-dated vaccines or mismatched stock levels

OPPORTUNITIES:

- Availability of free adult immunizations under Section 317 funding
- Universal purchasing programs, which allows for purchasing vaccines for both adults and pediatrics at lower costs by collecting funds from health plans, insurance companies and other payers up front
- Training and technical assistance around vaccine storage and inventory management systems to assist with workflow and cost
- Focus on adult immunizations as a quality improvement measure similar to the pediatric measures currently required in the Patient-Centered Medical Home recognition process (ARQI1, NCQA Standards 2017)

This white paper begins with an overview of FQHCs, including what makes them unique among primary care providers. It then discusses six areas of FQHC policy that impact their efforts to increase adult immunization rates:

- Statutory and HRSA Requirements for FQHCs
- FTCA: Federally-Supported Medical Malpractice Insurance for FQHCs
- Medicaid
- Medicare
- Pharmacy
- Section 340B Drug Discount Program
- Veterans

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For each policy area, we provide background information followed by strategies to potentially increase adult immunization rates.

WHAT MAKES FQHCs UNIQUE?

Federally Qualified Health Centers (FQHCs) – commonly referred to as Community Health Centers – are the backbone of America's primary care safety net. With over 12,000 sites nationwide, health centers provide high quality, affordable primary care to over 28 million medically-underserved individuals.

By law and by mission, all health centers:

- **Target the neediest individuals:** By law, all FQHCs serve high-need areas or populations, where poverty is high and/or caregivers are scarce. Nationally, 48% of FQHC patients are on Medicaid, 23% are uninsured, 10% are on Medicare, and of the 18% who have private insurance, many struggle to meet their deductibles and copays.
- **Offer a broad range of health care and enabling services:** FQHCs offer a broad range of services - medical, dental, behavioral, and preventive. They also provide services that enable individuals to access health care services appropriately (e.g., translation, health/nutrition education, community outreach, transportation, and patient case management), even though they are rarely covered by insurance.
- **See all patients regardless of ability to pay:** FQHCs offer the full range of services to every individual, regardless of insurance status, income, diagnosis, language, or other factors. Almost 70% of health center patients have incomes below the Federal Poverty Level (FPL); if these individuals are uninsured or underinsured, they pay no more than a nominal fee. Another 23% of FQHC patients have incomes between 101% and 200% FPL; if uninsured or underinsured, these individuals are charged based on a sliding fee scale.
- **Are Community-based and governed:** Each FQHC is governed by a patient-majority board, which ensures that it is both reflective of and responsive to the unique needs of its community. The fact that FQHCs are rooted in their communities makes them a trusted provider among the medically vulnerable populations they serve.

STATUTORY AND HRSA REQUIREMENTS FOR FQHCs

Background

FQHCs must adhere to the requirements laid out in Section 330 of the Public Health Service Act, and overseen by HRSA[2]

To qualify as a FQHC, a clinic must generally be determined by the Federal government as meeting the requirements outlined in Section 330 of the Public Health Service Act ("Section 330").

The Section 330 Program is overseen by the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services. Within HRSA, the unit charged with Section 330 administration and oversight is the Bureau of Primary Health Care (BPHC).

Section 330 requirements are extensive and are laid out in detail in the Health Center Compliance Manual produced by HRSA.[3] These requirements cover a wide range of issues, including clinical care, financial management, and governance.

Approximately 9% of FQHCs are required to focus on serving migrant and seasonal farmworkers, while another 9% are required to serve persons experiencing homelessness

Approximately 80% of FQHCs are required to focus on the needs of all medically underserved individuals in their service area. However, around 9% of FQHCs are required to focus predominantly on the needs of migrant and seasonal farmworkers, and another 9% to focus on individuals experiencing homelessness. Finally, around 1% of FQHCs are required to focus on the needs of residents of public housing. Note that all FQHCs must meet Section 330 requirements, regardless of the population they focus on.

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Section 330 explicitly requires FQHCs to provide immunizations

Section 330(b)(1)(A)(i)(III)(dd) states that all FQHCs are required to provide their patients with "immunizations against vaccine-preventable diseases".[4]

HRSA requires FQHCs to report annually on several vaccination measures

Section 330(k)(3)(I)(ii) requires FQHCs to report such data "as the Secretary may require". [5] Based on this authority, HRSA requires FQHCs to submit detailed, standardized quantitative data on an annual basis. This data set – called the Uniform Data System (UDS) – is posted online, and can be viewed at the national, state, and individual health center level.[6] UDS data addresses a broad range of issues, such as patient characteristics, clinical activities, and financial performance.

As part of their annual UDS submissions, FQHCs are required to report to HRSA on three activities involving immunization:

- The number and percentage of children 2 years of age who received age appropriate vaccines by their 2nd birthday.
- The total number of visits during which an influenza vaccine was provided, and the total number of patients who received it.
- The total number of visits during which other specified vaccines (e.g., MMR, DTap) were provided, and the total number of patients who received one or more of them.

The specific measures, along with calendar year 2018 national data, are below. Note that this data was based on a total patient population served of approximately roughly 27 million persons, of whom around 18 million were ages 18 and above.

From 2018 UDS Table 6B, Quality of Care measures[7]:

SECTION C - CHILDHOOD IMMUNIZATION STATUS				
Childhood Immunization Status		**Total Patients with 2nd Birthday (a)**	**Estimated Number of Patients Immunized (b)**	**Estimated % patients immunized (c)**
10.	Percentage of children 2 years of age who received age appropriate vaccines by their 2nd birthday	395,807	156,116	39.44%

From 2018 UDS Table 6A - Selected Diagnoses and Services Rendered[8]:

CATEGORY		**APPLICABLE ICD-10-CM CODE OR CPT4/II CODE**	**NUMBER OF VISITS (A)**	**NUMBER OF PATIENTS (B)**
24.	Selected immunizations: hepatitis A; haemophilus influenzae B (HiB); pneumococcal; diphtheria; tetanus; pertussis (DTaP) (DTP) (DT); mumps; measles; rubella (MMR); poliovirus; varicella; hepatitis B	CPT-4: 90632, 90633, 90634, 90636, 90643, 90644, 90645, 90646, 90647, 90648, 90669, 90670, 90696, 90697, 90698, 90700, 90701, 90702, 90703, 90704, 90705, 90706, 90707, 90708, 90710, 90712, 90713, 90714, 90715, 90716, 90718, 90720, 90721, 90723, 90730, 90731, 90732, 90740, 90743, 90744, 90745, 90746, 90747, 90748	5,167,756	3,795,759
24a.	Seasonal flu vaccine	CPT-4: 90630, 90653 through 90657, 90661, 90662, 90672, 90673, 90674, 90682, 90685 through 90688, 90749, 90756	4,874,190	4,437,040

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Please note the following points about the immunization measures from UDS table 6A & 6B (See page 5).

- The first set of measures is specific to children (2-year-olds.) The other two measures incorporate adults but could also include children. For example, the total number of influenza vaccines includes those given both to children and adults.
- The child measure (percentage of children who received age appropriate vaccines by their 2nd birthday) is a standardized, commonly-used measure; the National Committee for Quality Assurance (NCQA) is the "Measure Steward" and it is used by the Centers for Medicare and Medicaid Services (CMS). For more information, see page 192 of HRSA's 2018 UDS Manual.[9]
- In contrast to the child measure, the two measures that include adults (influenza and other vaccines):
  - Are not commonly-used measures. NCQA does not manage them, and neither Medicare nor Medicaid require them as standard measures.
  - Do not mirror National Vaccine Advisory Committee standards, in terms of linking specific vaccines to specific age groups or at-risk populations.
  - Are raw numbers as opposed to a percentage of the eligible patient population.

HRSA incentivizes FQHCs' performance on the childhood immunization measure, but not the immunization measures that include adults
Another important distinction between UDS immunization measures is the incentives for FQHCs to report complete and accurate data, and to demonstrates strong clinical performance.

Within the UDS, HRSA has identified a subset of measures as clinical quality measures (CQMs)[10]. For the past several years, HRSA has provided public recognition as well as supplemental grant funding[11] to FQHCs based on their performance on these CQMs. For 2017, funding and recognition were provided to:

- National Quality Leaders - FQHCs that exceeded national clinical quality benchmarks (including Healthy People 2020 goals[12]) for:
  - chronic disease management;
  - specific types of preventive care; and/or
  - perinatal/prenatal care (percent of women who received care in the first trimester, and percent of infants with low birth weight)
- Health Center Quality Leaders – FQHCs who achieved the best overall clinical performance among all health centers for CQMs.
- Clinical Quality Improvers - FQHCs who made at least a 10% improvement in one or more CQMs from year to year.

HRSA considers the childhood immunization measure to a CQM, and as a result it is one factor used to determine which FQHCs receive these recognitions and supplemental grant funding each year. In contrast, the two UDS measures that include adult immunizations are not considered CQMs, and there are no financial or programmatic consequences associated with performance on the measures.

Individuals who receive immunization(s) – but no other services – from an FQHC are not considered FQHC patients by HRSA
HRSA has a detailed definition about when an individual can be considered a "patient" for UDS purposes. For example, an individual who receives only an immunization(s) from an FQHC is not considered a FQHC patient. Note that in their applications to HRSA (which FQHCs must submit at least once every three years), FQHCs must indicate how many patients they expect to serve. HRSA closely monitors how FQHCs' actual patient numbers compare to their estimates, and some FQHCs are concerned that failure to reach their estimated number of patients could put some of their HRSA grant funding at risk in the future.

FQHCs likely under-report their actual immunization activity
There are reasons to suspect that FQHCs' UDS data around immunizations – particularly adult immunizations – may understate their actual activities in this area. These include:

- *Documentation does not "roll up" into aggregate data:* Many FQHCs document immunizations in a free-text entry field in the electronic medical record. As data entered in free-text fields does not "roll up" into aggregated data, this suggests that immunization rates could be significantly understated.
- *Immunizations provided to "non-patients" may not be counted:* Many FQHCs engage in community health fairs and outreach campaigns through which they offer immunizations to the general public. As discussed above, individuals who are vaccinated at these types of events

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are not counted as patients unless they receive other health care services from the FQHC. For this reason, some FQHCs may not include vaccines provided at such events in their UDS reports.[13]

Section 330-related strategies to increase adult vaccination rates among FQHC patients:

1. ***HRSA could add a composite adult immunization measure(s) to the data that FQHCs must report annually to HRSA.***

Including a measure of adult vaccination in UDS would likely encourage FQHCs to expand their focus on this issue. One option would be for HRSA to adopt the following composite measure, which is currently being used in the Indian Health Service:

Vaccines Included in Adult Immunization Composite Measure

AGE GROUP	VACCINES INCLUDED	OPTIONAL
19–59	Tdap ever; Tdap or Td within 10 years	Influenza
60–64	Tdap/Td; Zoster	Influenza
≥65	Tdap/Td; Zoster; Pneumococcal polysaccharide-23 (PPSV-23) or pneumococcal conjugate (PCVS-13)	Influenza

Another option would be the new Healtcare Effectiveness Data and Information Set (HEDIS) composite measure of prenatal immunization status, which indicates the percentage of deliveries during the measurement period in which women received both an influenza and Tdap vaccine.[14]

A potential first step towards getting one or both of these measures added would be for staff from the CDC and other federal agencies to reach out to HRSA to discuss the issue. Also, the fact that many FQHCs' EHRs undercount immunization activity (as discussed) suggests that EHR changes might be necessary to ensure complete data.

2. ***HRSA could consider performance on the adult immunization measure when determining which FQHCs receive supplemental grant funding and/or public recognition.***

As discussed above, HRSA provides public recognition and supplemental grant funding[15] to FQHCs who perform well on specified clinical quality measures (CQM). For example, funding has been awarded based on FQHCs' overall performance on CQMs, and specifically on their performance related to preventive care CQMs.

HRSA could make a measure of adult immunization an official CQM. (Note that the childhood immunization measure is already a CQM.) Once this is done, performance on this measure would automatically be considered when HRSA rewards FQHCs for overall clinical performance. HRSA could also choose to make awards based specifically on this measure (alone, or in combination with related measures such as those involving preventive care.) As discussed above, HRSA already makes awards based on specific areas of CQMs, such as prenatal and perinatal care.

Current work being done by the National Committee for Quality Assurance (NCQA) includes the proposal of adding both an Adult Immunization Status and Prenatal Immunization Status HEDIS measure. The Adult Immunization measure includes the percentage of patients 19 years of age and older who are up-to-date on recommended routine vaccines—Influenza, Td or Tdap, Herpes zoster and Pneumococcal. The prenatal immunization measure looks at the percentage of deliveries during the measurement period in which women received an influenza and/or Tdap vaccines. Work is ongoing and no data has been published to date (September 2019), but this could be a blueprint for HRSA to develop similar measures.

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3. ***Outside groups could incentivize FQHCs to focus on adult immunization by offering funding and/or public recognition linked to adult immunization rates.***

Even if HRSA agrees to add an adult immunization measure to mandatory UDS reporting, and to consider performance on this measure when rewarding clinical performance, it would still take several years for these changes to go into effect. In the shorter term, outside groups could incentivize FQHCs to focus on adult immunization by offering funding and/or public recognition to those who significantly expand their activity and performance in this area. These funders could work directly with individual FQHCs, or could work through FQHC organizations such as:

- State-based associations of FQHCs, called Primary Care Associations (PCAs)[16]
- Organizations that represent FQHCs serving high-risk populations, such as migrant and seasonal farmworkers, and individuals experiencing homelessness. [17]
- Also, as previously mentioned, EHR changes might be needed to ensure that adult immunization data can be effectively aggregated.

4. ***Outreach and support could target FQHCs that focus on specific at-risk populations.***

As stated above, around 9% of FQHCs focus predominantly on the needs of migrant and seasonal farmworkers, and another 9% focus on individuals experiencing homelessness. Working directly with these FQHCs – and the organizations that represent them– could provide an efficient means of reaching their at-risk populations.[18]

For example, the Advisory Committee on Immunization Practices (ACIP) recommends the routine use of Hepatitis A vaccine for persons experiencing homelessness. Outreach to FQHCs who focus on such individuals (often called "Health Care for the Homeless grantees"), as well as to their national organization, could be an efficient route to target these persons.

HRSA has cooperative relationships with groups representing FQHCs that serve migrant and seasonal farmworkers, and persons experiencing homelessness, and would likely facilitate connections with these groups if requested.[19]

FTCA: FEDERALLY-SUPPORTED MEDICAL MALPRACTICE INSURANCE FOR FQHCS

Background

Section 330 grantees receive free medical malpractice insurance through the Federal Tort Claims Act (FTCA)
FQHCs that receive grant funding under Section 330 of the Public Health Service Act (the "grantees", which represent roughly 85% of all FQHCs) also receive free medical malpractice insurance through the federal government. This coverage is provided through the FTCA, and it applies to the FQHC's employees and contractors, as well as volunteer providers whom the FQHC has registered with HRSA.

The federal government has detailed rules about which patients, services, and providers are covered under FTCA, and FQHCs must purchase supplemental insurance to cover activities that which are not eligible for FTCA coverage.

FTCA malpractice coverage applies to community-focused immunization campaigns
As a general rule, FTCA only covers services provided to individuals who have a face-to-face visit with a provider at a standard FQHC location. However, HRSA makes an explicit exception to this rule for community-focused immunization campaigns. In its FTCA Policy Manual[20], HRSA states explicitly that FTCA coverage applies when "On behalf of the health center, health center staff conduct or participate in an event to immunize individuals against infectious illnesses. The event may be held at the health center, schools, or elsewhere in the community."

FTCA malpractice coverage is available for clinicians who volunteer at FQHCs
Clinicians frequently cite the lack of malpractice coverage as a barrier to volunteering their services. Fortunately, Congress recently eliminated this barrier for FQHCs. Since late 2017, clinicians who volunteer at FQHCs can receive FTCA coverage, provided that the FQHC submits the appropriate documentation to HRSA in advance.[21]

FQHCs can bill insurers – including Medicaid and Medicare – for services provided by volunteer clinicians in the same manner that they bill for services provided by employees and contractors. (This ability predates the 2017 law extending FTCA to qualified volunteer providers.)

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FTCA-related strategies to increase adult vaccination rates among FQHC patients:

1. ***Educate FQHCs that FTCA coverage applies to community events, such as immunization fairs.***

   FQHC grantees frequently cite the lack of FTCA coverage as a barrier to engaging in specific activities and may assume that FTCA does not cover immunization campaigns because HRSA does not consider the persons being immunized as patients of the FQHC. Educating FQHCs that FTCA coverage covers immunization campaigns – and even pointing out the specific mention of these events in HRSA policy documents – may encourage more FQHCs to engage in these activities.

2. ***Encourage FQHCs to recruit volunteer clinicians to assist with immunization efforts,highlighting the availability of free malpractice coverage.***

   The availability of free malpractice insurance can be an effective tool for recruiting clinicians to volunteer with FQHCs, as it removes one of the major barriers that many clinicians express about volunteering. Community-based immunization events could be a first step for getting clinicians to volunteer with FQHCs, as they are time-limited. Also, a volunteer clinician could also serve as an "immunization champion" within a FQHC, with responsibility to develop and implement strategies to increase adult immunization rates.

   Note that if a volunteer clinician is one of the types whose services trigger a PPS payment under Medicare or Medicaid (see discussion below[22]), then the FQHC can receive reimbursement for that clinicians' services, even if he or she provides immunization-only visits.

MEDICAID

Medicaid is the largest source of insurance coverage for FQHC patients in every state. While the exact percentage of FQHC patients who have Medicaid varies by states - due to variations in Medicaid expansion and other eligibility policies – nationally Medicaid covers almost 50% of FQHC patients. For this reason, any effort to increase adult immunization rates among FQHC patients must reflect a thorough understanding of how Medicaid reimburses for adult immunization in the FQHC setting.

While researching this report, the most common barrier to increasing adult immunization rates among Medicaid patients by FQHCs that was reported annecdotely was the lack of Medicaid reimbursement. Technically, Medicaid does pay FQHCs for vaccines, as it includes a small amount of reimbursement towards these costs every time it provides a per-visit payment under the FQHC Prospective Payment System. However, since immunization-only visits with providers such as nurses and pharmacists generally do not result in a PPS per-visit payment, FQHC staff often do not recognize that they are being reimbursed for these costs.

To explain how Medicaid pays FQHCs for immunizations – and the challenges in implementing strategies that might seem straightforward – this section begins by explaining Medicaid's systems for reimbursing FQHCs, called the Prospective Payment System. It also explains how reimbursement for adult immunization is incorporated into the PPS. This is followed by a discussion of payment-related strategies that have been proposed for increasing adult immunization under Medicaid (e.g., allow nurse-only visits), and examines their feasibility under PPS rules.

Background

How FQHCs are Reimbursed Under Medicaid

The FQHC Medicaid PPS rate

Most free-standing outpatient providers are reimbursed for services provided to Medicaid recipients according to the Medicaid fee schedule. Under this approach, providers submit a claim for each visit, which lists the Current Procedural Terminology (CPT) billing codes for every service provided during the visit. The Medicaid agency has a specific reimbursement amount associated with each CPT code, and reimburses the outpatient provider accordingly. For example, if a claim contains three CPT codes (indicating that three distinct services were provided), Medicaid will determine the payment associated with each code, total them, subtract any patient copay amount, and reimburse the provider the remainder. Thus, the reimbursement for each visit varies based on which CPT codes were listed, and the reimbursement amount associated with each.

Federal law requires state Medicaid agencies to reimburse FQHCs and Rural Health Clinics (RHCs) differently from most free-standing outpatient providers. Section 1902(bb) of the Social Security Act establishes a unique payment system for FQHCs and RHCs. Under this system – commonly referred to as the Prospective Payment System (PPS) – FQHCs and RHCs are paid a single rate for each billable visit, regardless of the number or type of services provided during that visit. Thus, Medicaid pays an FQHC the same amount for a visit that generates only a single CPT code as for visit which

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includes multiple services such as laboratory work, X-rays, and immunizations. This per-visit payment rate is known as the FQHC's PPS rate, and it is meant to reflect the health center's average cost per billable visit.

How FQHC Medicaid PPS rates are calculated

Federal statute requires that each FQHC have a unique Medicaid PPS rate, calculated using its own data from a base year. This rate is calculated as follows:

1. Select a base year(s), which is the year whose data is used to calculate the FQHC's PPS rate. (When the PPS was originally implemented in 2002, the statute required using 1999 and 2000 as the base years.)
2. Determine the total cost to the FQHC to provide all Medicaid-covered services to all Medicaid patients during the base year. See below for more information about what costs must, may – and may not – be included in this calculation.
3. Determine how to define a "billable visit." Federal law requires that all face-to-face encounters with at least six types of providers - physicians, physician assistants, nurse practitioners, certified nurse-midwife, clinical psychologists, and clinical social workers – qualify as billable visits. However, beyond this requirement, states have significant flexibility in how to define a billable visit – see below for more information.
4. Divide total costs by total visits, to determine an average per-visit rate.

In mathematical terms:

$$\frac{\textbf{Total Allowable Costs}}{\textbf{Total Billable Visits}} = \textbf{PPS Rate (aka average cost per billable visit)}$$

Once PPS rates are calculated for the base year, the statute requires that they be updated annually using the Medicare Economic Index (MEI), to reflect inflation. The statute also requires states to update PPS rates – meaning to determine new rates using cost and visit data from a more recent year – every time there is a significant change in the scope or intensity of the services that the FQHC provides. As discussed below, there is significant variation across state Medicaid agencies in how closely this comply with the rate update requirements laid out in statute.

How a "billable visit" is defined under the FQHC Medicaid PPS

Federal law requires that any visit that includes a face-to-face interaction with at least one of the six types of core providers (physicians, PAs, NPs, CNMs, clinical psychologists, and clinical social workers) must count as a billable visit.

Beyond this basic requirement, state Medicaid agencies have flexibility in how to define a billable visit. For example:

- FQHC patients will often have face-to-face encounters with both a physical health provider and a mental health provider on the same day. Each state's Medicaid agency decides whether to allow the FQHC to bill for one PPS payment or two for that patient that day.
- Many state Medicaid programs cover services from outpatient providers beyond the six "core" types listed above – e.g., marriage and family therapists, licensed professional counselors. In these situations, federal law requires that the costs associated with these additional provider types be included in the calculation of each FQHC's PPS rate (i.e., in the numerator above). However, each state can decide whether to count face-to-face encounters with these providers as "billable visits" (i.e., in the denominator above.)

Relevant to the discussion of adult immunizations, states have the option to count nurse-only and pharmacist-only visits as billable visits but are not required to do so. See discussion below on the steps involved in establishing nurse-only or pharmacist-only visits once a PPS rate has been established.

How the definition of a billable visit impacts PPS rates

How a billable visit is defined has a direct impact on a FQHC's PPS rate. In general, the broader this definition is, the more billable visits a FQHC will have for the same total costs – and the lower its per-visit (PPS) payment rate will be.

For example, consider a hypothetical FQHC whose total costs for Medicaid patients in one year is $1,000. During that year, Medicaid patients had 10 visits with a physician, and 2 with a registered nurse. If billable visits are defined as only encounters with physicians, then this FQHC had 10 billable visits during the year, yielding a PPS rate of $100 per visit ($1,000 allowable costs divided by 10 billable visits). If nurse-only visits were included as billable, then the FQHC had 12 billable visits, yielding a PPS rate of $83.33 per visit.

Congress created the PPS to ensure that FQHCs receive the same amount of total reimbursement over the course of a year (assuming that the breakdown of costs and visits remains constant) regardless of how billable visit is defined. In the above example, the FQHC receives the same total payment from Medicaid – $1,000 – under both definitions of billable visit. However, which definition is used determines whether they receive that amount in the form of 10 payments of $100 each, or 12 payments of $83.33 each.

An analogous situation is cutting up a pizza. You can cut a pizza into 8 slices or 12 slices, but the more slices you

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make, the smaller each slice becomes. Also, the total size of the pizza remains the same size, regardless of whether it was cut into 8 or 12 slices.

In other words, the more broadly billable visit is defined, the lower a FQHC's per-visit (aka PPS) rate becomes. Also, per the statute, any changes to the definition of a billable visit require that FQHCs' PPS rates be recalculated, as existing PPS rates reflect the current definition of a billable visit. Failure to recalculate PPS rates when expanding the definition of billable visits will result in the PPS rate being too high, resulting in higher Medicaid spending. In the example above, if nurse-only visits were made billable without changing the PPS rate, then the FQHC would receive 12 payments of $100 each, for a total of $1,200 – which exceeds the total amount of reimbursement that the PPS is intended to provide.

There are no regulations regarding the Medicaid FQHC PPS, and compliance and enforcement is inconsistent

While the FQHC Medicaid PPS was enacted in 2000 and became effective in 2002, CMS has never issued regulations clarifying how it is to be implemented. The only official document issued by CMS was a set of FAQs.[23]

There is significant variation in how state Medicaid agencies implement and comply with the PPS statute. For example, some states have never recalculated PPS rates since they were initially calculated in 2001, despite the explicit statutory requirement to do so every time there is a significant change in the "scope or intensity" of services provided. Other states have imposed limits on PPS rates, and FQHCs have sued to have the limits removed, with varying degrees of success depending on the type of limit imposed. In addition, we are aware of at least one state that pays FQHCs the fee schedule amount for each nurse-only immunization visit. This approach is not permissible under the statute, for reasons that will be discussed below.

States can reimburse FQHCs using an alternative to the PPS, but any "Alternative Payment Method" (APM) is subject to statutory requirements

The statute creating the PPS authorizes states to establish an Alternative Payment Methodology (APM) for FQHCs, to be used in place of the PPS. Per the statute, any APM must meet the following two requirements:

- Total payments under the APM must be at least the same as total payments would have been under the PPS, and
- Each FQHC to whom the APM would apply must agree to the alternative system.

As will be discussed below, these requirements can add significant complexity to states' efforts to implement an APM.

Adult Immunizations and the FQHC Medicaid PPS

Medicaid does pay FQHCs for adult immunization – but indirectly in most states.

Technically, it is inaccurate to state that "Medicaid doesn't pay for adult immunization." As discussed below, all costs associated with adult immunization (including vaccine cost, supplies, and provider time) are included in the total allowable costs used to calculate a FQHC's PPS rate.

As a simplified example, imagine a FQHC whose total costs – excluding adult immunization – were $1,000 in their base year. If that FQHC had 10 billable visits per year, then their PPS (without adult immunization) would be $100 per visit. Now assume their adult immunization costs for the base year were $50, bringing total costs to $1,050, across the same 10 billable visits. Now the PPS rate is $105. In other words, the FQHC gets an additional $5 for every visit to help cover its overall costs to provide adult immunization - regardless of whether any adult immunizations were provided during a specific visit.

This is why policy officials at CMS and state Medicaid agencies disagree with claims that "Medicaid does not pay for immunizations at FQHCs." They point out that funding to cover adult immunization costs is included in every PPS payment.

On the other hand, from the FQHC perspective, it can seem like Medicaid does not pay for adult immunization because:

- The FQHC gets paid the same amount for a patient visit with a provider, regardless of whether or not immunizations are given, and
- If a patient has a separate appointment just to get immunizations, such as with a nurse or a pharmacist, FQHCs generally are not permitted to claim this as a billable visit – and thus do not receive any additional Medicaid payment for this appointment. (The only exception is the few states which pay for nurse-only or pharmacist-only visits, as described previously.)

Federal law requires immunization costs to be factored into – and reimbursed via – PPS rates.

The Medicaid statute requires that the total costs used to calculate PPS rates must include at a minimum the costs associated with:

- services provided by six core provider types – physicians, PAs, NPs, CNMs, clinical psychologists, and clinical social workers.
- services and costs that are incident to services provided by the six core provider types.
- any other ambulatory services that the FQHC offers and the state Medicaid program covers. For example, this could include other types of providers, such as marriage and family therapist and licensed professional counselors.

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Immunizations are considered incident to services provided by physicians and therefore must be included in PPS calculations. Thus, all costs associated with adult immunization (including vaccine cost, supplies, and provider time) must by law be included in the total allowable costs used to calculate a FQHC's PPS rate. This is similar to how other services that do not generate a face to face visit are treated; the costs of those services are included in the total cost calculation, which is used to generate the PPS rate.

Thus, under federal law, state Medicaid agencies may not reimburse for adult immunization services outside of the PPS system. This leaves them with two options for how to handle immunization-only visits: either make them billable visits under PPS or do not reimburse separately for them. Legally, states do not have an option to reimburse for immunization-only visits at a rate other than PPS.

Immunization-only visits are generally not billable visits under the FQHC Medicaid PPS.
Typically, immunizations are considered incident to the services of a core provider (e.g., physician) and thus immunization-only visits do not qualify as billable visits that trigger a PPS per-visit payment. The only exceptions are:

1. If the immunizations are provided by one of the six "core" provider types (e.g., physician, PA, NP) whose services automatically trigger a billable visit per Federal statute

   OR

2. If the immunizations are provided by a nurse or pharmacist, and the state Medicaid agency considers nurse-only or pharmacist-only visits to be billable visits.

Regarding #1, FQHCs generally do not consider providing immunization-only visits to be the most effective use of "core" providers' time. Regarding #2, most states do not consider nurse-only or pharmacist-only visits to be billable. As discussed in the following section, it is technically possible to change state Medicaid policy in order to make such visits billable; however, this would be a major undertaking that would raise many issues far beyond adult immunization

To make immunization-only visits with nurses and pharmacists separately billable for FQHCs, states must (re)calculate each FQHC's PPS rate.
Federal statute gives state Medicaid agencies the option to allow FQHCs to bill separately for immunization-only visits with nurses or pharmacists (hereafter referred to as "nurse/pharmacist immunization-only visits"). However, when implementing this option, the state must comply with these two statutory requirements:

- Payment for these visits must be made via the PPS, not the fee schedule, and
- Immunization-only visits must be included in the calculation of PPS rates.

As discussed above, making nurse/pharmacist immunization-only visits separately billable under PPS will increase the total number of visits in the PPS calculation (the denominator in the equation above) - which in turn decreases the per-visit PPS payment. If PPS rates are not adjusted to reflect this higher number of visits, then total payments to FQHCs would increase above total reasonable costs – which would be inconsistent with the statute (and also likely to be opposed by both the state Medicaid agency and CMS).

For this reason, deciding to make nurse/pharmacist immunization-only visits separately billable under PPS would require a state to recalculate all its FQHCs' PPS rates. Depending on the state, recalculating these rates often entails significant administrative effort and potential costs for the Medicaid agency, for reasons unrelated to adult immunizations.

The level of administrative effort and the financial impact involved in recalculating FQHCs' PPS rates varies by state. Some states are proactive about adhering to the statutory requirement to update their PPS rates when there are changes in the types of services health centers provide; for example, Arizona recalculates these rates every three years. In states like this:

- The Medicaid agency already has a "change in scope" process in place to handle the administrative tasks involved in updating rates (e.g., collecting and analyzing costs reports).
- Changes in reasonable costs – including those due to inflation and to changes in scope and intensity – have been factored into PPS rates regularly, so there is unlikely to be a large gap between the costs on which current PPS rates were based and reasonable costs at present.
- The Medicaid agency is more likely to have already considered requests from other groups that are interested in changing the PPS methodology (e.g., other provider types that would like to qualify for billable visits, such as marriage and family therpasits and licensed profession counselors).

In these types of states, convincing policymakers to make nurse/pharmacist immunization-only visits separately billable would be relatively straightforward, because the administrative, policy, and financial impacts would be relatively small.

However, other state Medicaid agencies have not updated their FQHC PPS rates in many years, and/or

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have updated the rates for only a few FQHCs. Medicaid agencies in these states would face many administrative and financial hurdles to updating PPS rates.

To determine the level of effort involved in recalculating FQHC PPS rates in a specific state, individuals are strongly encouraged to contact the state association of FQHCs, often called the "Primary Care Association" (PCA). Contact information for each state's PCA is available online.[24]

Medicaid strategies to increase adult vaccination rates among FQHC patients

1. ***Make nurse/pharmacist immunization-only visits billable visits under the FQHC Medicaid PPS***
   As discussed, state Medicaid agencies have the option to count nurse/pharmacist immunization-only appointments as billable visits which result in a PPS (aka per-visit) payment to the FQHC.

   However, few states take advantage of this option, as adding a new category of billable visit requires recalculating each FQHC's PPS rate – which can entail significant administrative and financial costs for many states. To determine the impact and likelihood of success in a specific state, individuals interested in this approach are strongly encouraged to contact the state's PCA.

2. ***Permit FQHCs to bill for immunization-only visits <u>outside</u> of the FQHC PPS, using an alternate payment method (APM)***
   While the PPS statute requires that immunization costs be included in PPS calculations, State Medicaid agencies could establish an APM where immunizations are removed from the PPS calculations and reimbursed separately.

However, establishing this type of APM would be a significant undertaking for a state – even more significant than making nurse/pharmacist immunization-only visits separately billable under PPS. Among other steps, the state Medicaid agency must:

- Obtain the approval of each participating FQHC.
- Recalculate FQHCs' PPS rates to remove the costs of immunizations. This entails all the steps outlined above.
- Determine and implement a new methodology to reimburse for immunizations.
- Ensure that the new system will not decrease total reimbursement to the FQHCs.
- Obtain CMS approval for the change.

In addition, as discussed above, any effort to adjust the FQHC payment system could open a range of other issues unrelated to immunization. As a result, it is unlikely that a state Medicaid agency would want to pursue this approach simply as a way to increase adult immunization rates.

MEDICARE

The Medicare PPS for FQHCs

How the Medicare FQHC PPS compares to the Medicaid FQHC PPS
As in Medicaid, Medicare reimburses FQHCs using a flat, predetermined amount for each billable visit. This system – which is also called a PPS, as in Medicaid – is relatively new, having been implemented in 2014 and 2015. (In contrast, the Medicaid FQHC PPS was implemented in in 2002.)

The Medicare PPS has some significant differences from the Medicaid PPS. Most notably:

- Medicare has a single Medicare PPS rate for all FQHCs across the country. This national rate varies only as follows:
  - It is adjusted slightly to reflect cost differentials in different geographic areas;
  - It is increased by 34.16 percent when a patient is new to the FQHC, or an initial preventive physical exam (IPPE) or annual wellness visit (AWV) is furnished; and
  - Medicare has standardized, national rules regarding which types of visits trigger a PPS payment (in other words, what constitutes a billable visits).

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The Medicare PPS rate was set using a similar methodology as the Medicaid PPS rates, except that it was done on a national level, instead of a FQHC-specific level. CMS took total allowable costs for all FQHC services provided in a base year and divided them by total billable visits (as they defined that term). The result was the national Medicare PPS rate. Only encounters that meet the definition of a billable visit trigger a Medicare PPS per-visit payment.

How a billable visit is defined under the FQHC Medicare PPS
Medicare defines a billable visit as a face-to-face interaction with at least one of the six types of core providers (physicians, PAs, NPs, CNMs, clinical psychologists, and clinical social workers). Importantly – and unlike under Medicaid – face-to-face visits with certified diabetes self-management training (DSMT) providers, and with medical nutrition therapy (MNT) providers also count as billable visits. DSMT providers may include registered nurses, registered dietitians/nutritionists, pharmacists, or other healthcare professionals holding certification as a diabetes educator (CDE) or board certification in advanced diabetes management (BC-ADM). MNT may be provided by a registered dietician or nutritionist.

Since Medicare is a national program, there is no state flexibility to expand the definition of billable visits, as there is in Medicaid. Additional information on the Medicare FQHC can be found on their website.[25]

Adult Immunizations and Medicare Reimbursement

The costs of most – but not all – immunizations are included in FQHCs' PPS rates
With two important exceptions, the cost of all immunizations are included in FQHCs' Medicare PPS rates. The two exceptions are influenza and pneumococcal vaccines, which FQHCs can bill and be reimbursed for separately from (and in addition to) their PPS payments, via the annual cost report process. (See the next section for a discussion of the cost report process.)

This is different from how Medicare reimburses most outpatient providers for vaccines. For non-FQHCs, Medicare reimburses them directly for influenza, pneumococcal, and hepatitis B vaccines under Part B, and for other vaccines under Part D. However, FQHCs are not permitted to bill for any vaccines under Part D, or under standard Part B processes; rather, influenza and pneumococcal vaccines are reimbursed via the annual cost report, and other vaccines are folded into PPS reimbursement rates.

How FQHCs are reimbursed for the costs of influenza and pneumococcal vaccinations
Medicare reimburses FQHCs for influenza and pneumococcal vaccination through their annual cost reporting process. At the end of its 12-month cost reporting period, each FQHC is required to submit a cost report to their Medicare Administrative Contractor (MAC). In this report, they can list 100 percent of their reasonable costs associated with both the vaccines themselves and for administering them. Once the MAC reviews and approves the cost report, the FQHC is reimbursed for their vaccine-related costs.

Due to this reimbursement structure, FQHCs can face significant delays between the time influenza and pneumococcal vaccines are provided and when they receive Medicare reimbursement. As stated above, each FQHC's Medicare cost reporting period (CRP) is 12 months, and FQHCs have 5 months following the end of a CRP to submit their cost report to the MAC.[26] The MAC then typically takes several weeks to review the report and issue reimbursement. Thus, up to 18 months can pass between the time an influenza or pneumococcal vaccine is administered to a Medicare patient and when the FQHC receives the reimbursement.

Payments for chronic care management and virtual check-ins do not cover adult immunization
In recent years, Medicare has proposed and/or begun reimbursing FQHCs for specific activities that do not involve a face-to-face encounter between a provider and patient. These activities include various care management activities for patients with complex chronic illnesses (called chronic care management) and virtual check-ins with patients via the phone, etc. None of these these activities involve face-to-face interactions, immunization cannot be incorporated into them.

Medicare-related strategies to increase adult vaccination rates among FQHC patients:

1. ***FQHCs could maximize nurse/pharmacist visits for influenza and pneumococcal vaccines for Medicare patients***
   Because reimbursement for influenza and pneumococcal vaccines is made outside of the Medicare PPS, this reimbursement is not subject to the PPS rules around billable visits. In other words, the FQHC is reimbursed separately for these services, regardless of whether they are provided in conjunction with a face-to-face visit with a billable provider, such as a physician. For this reason, FQHCs can focus on maximizing the use of nurse/

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pharmacist visits for influenza and pneumococcal vaccines with the knowledge that they will be fully reimbursed for these services.

2. ***To reduce the delays in reimbursement for influenza and pneumococcal vaccines, CMS could permit FQHCs to bill for these vaccines under the Part B fee schedule at the time of service, as long as these interim payments are later reconciled with their Cost Reports***
CMS could permit FQHCs to bill Part B directly for the cost of these vaccines immediately following the date of service; this is similar to how FQHCs bill for other services covered under Part B. The MACs could then provide interim reimbursement to the FQHC based on national fee schedule rates for these vaccines. However, if this approach were pursued, it is important that these interim payments be reconciled to the FQHCs' reasonable costs during the cost reporting process, so that FQHCs are made whole for any costs that exceed the fee schedule reimbursement.

3. ***FQHCs can leverage Medicare visits for diabetes self-management therapy (DSMT) and medical nutrition therapy (MNT) to address vaccination***
Providers of DSMT and MNT are considered billable providers under the FQHC Medicare PPS, meaning that the one-on-one services they provide trigger a per-visit PPS payment. Some, but not all, DSMT and MNT providers are eligible to provide vaccinations themselves. Nonetheless, FQHC's could use these visits as an opportunity to increase adult immunization rates by either:

- encouraging DSMT/MNT providers to discuss and refer their patients for immunizations, or
- having qualified providers administer vaccinations in conjunction with these visits, or administer themselves if within their scope of practice

As discussed above, FQHCs receive separate reimbursement to cover their full costs of providing influenza and pneumococcal vaccines – even if they are provided in conjunction with a billable visit, such as for DSMT or MNT.

PHARMACY

Background

A growing percentage of FQHCs have in-house pharmacies, and many of these serve non-FQHC patients
While the exact percentage is not known, it is estimated that at least one-third of FQHCs have in-house pharmacies. The term in-house means that the pharmacy is owned and operated by the FQHC; such pharmacies can be co-located with a care delivery site, or at a separate location. Some in-house pharmacies are "closed-door", meaning that they serve only the FQHCs' patients, while others are "open-door", meaning that they also serve members of the general public.

A growing number of FQHCs are implementing clinical pharmacy programs
Clinical pharmacists generally work directly with physicians, other providers, and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes. A small but growing number of FQHCs are implementing clinical pharmacy programs, often with a special focus on controlled substances and patients taking multiple medications. These clinical pharmacists often work collaboratively with patients' core providers to make medication changes, request lab work, or add additional therapeutic modalities.

Pharmacy-related strategy to increase adult vaccination rates among FQHC patients:

FQHCs could expand the role of in-house pharmacists in recommending and administering adult vaccines
According to recent research, 14% of all vaccines provided to FQHC patients were administered by in-house pharmacy staff. Given that at least one-third of FQHCs currently have in-house pharmacies, this suggests that there may be opportunities for FQHCs to expand adult immunization rates by expanding the role of in-house pharmacists in this process. Specifically, in-house pharmacists can potentially:

- Review patient records to determine which vaccines might be appropriate for each patient;
- Recommend specific vaccines to patients and/or their care providers; and
- Administer vaccines.

FQHCs considering this strategy should consider the following:

- *Variations in state law:* While most states allow pharmacists to provide immunizations, there are important differences in states' rules on

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issues such as the age of the patient, whether a prescription must be provided, etc.[27]

- *Medicaid:* As discussed above, costs associated with adult immunization are incorporated into Medicaid PPS (aka per visit) payment rates, and in most states Medicaid will not make a separate PPS payment for services provided by a pharmacist. (This is similar to the discussion about nurse-only visits.)
- *Medicare:* As discussed in the section on Medicare:
  - Medicare prohibits FQHCs - and their pharmacists – from billing Part D for vaccines.
  - For influenza and pneumococcal vaccines, Medicare Part B covers the FQHC's full costs, including for vaccines administered by pharmacists (and nurses). These payments are made separately from the PPS system, and there can be a significant lag in receiving reimbursement.
  - For other covered vaccines, Medicare does not provide separate reimbursement; they trigger a PPS payment only if they are provided as part of a face-to-face visit with a billable provider.
- *Cost-Benefit Analysis:* FQHC leadership should evaluate the cost and benefits of having pharmacists provide immunizations, as opposed to other uses of their time (e.g., filling prescriptions). FQHC pharmacists report anecdotally that from a financial perspective, they can earn significantly more revenue filling prescriptions than by spending the same amount of time providing immunizations.

THE 340B DRUG DISCOUNT PROGRAM

Background

While the 340B program does not include vaccines, FQHCs can access significant discounts on vaccine purchases through the 340B Prime Vendor

Section 340(b) of the Public Health Service Act requires pharmaceutical manufacturers to provide upfront discounts to FQHCs and other eligible safety net providers. By reducing how much FQHCs must pay for drugs, the 340B program is critical to their ability to provide their medically underserved patients with access to affordable medication. However, the 340B program is limited to drugs, and does not mandate discounts on vaccines.

Nonetheless, FQHCs' participation in a key element of the 340B program enables them to access significant discounts on vaccine purchasers. As part of the 340B program, HRSA has an agreement with Apexus, which serves as the 340B Prime Vendor Program (PVP).[28] The PVP negotiates discounts on 340B drugs, supplies, and vaccines on behalf of the approximately 90% of 340B providers that are PVP members. Because of its size, and its ability to leverage competition among distributors and manufacturers, the PVP is able to negotiate additional discounts – beyond those typically provided to small clinics. Apexus passes these discounts onto the 340B providers in the form of lower purchase prices for drugs and vaccines.

Even though vaccines are not subject to mandatory 340B discounts, Apexus has used its purchasing power to negotiate substantial discounts on them as well. These discounted prices are available exclusively to 340B providers and are the same regardless of the size of the organization. Thus, Apexus enables even the smallest FQHC to purchase vaccines at a significantly discounted rate.

340B-related strategy to increase adult vaccination rates among FQHC patients

Many FQHCs could likely reduce their costs to purchase vaccines by obtaining them through 340B Prime Vendor program (called Apexus)

A recent study indicated that the majority of FQHCs purchase vaccines directly from the manufacturer or distributor, as opposed to via a group purchasing organization. As the HHS National Vaccine Program Office recently stated, "Vaccine product pricing can vary as much as 3-fold depending on negotiated prices, which are confidential." Given this, it is likely that purchasing vaccines through Apexus could lower purchase costs for many FQHCs.

The PVP has full-line vaccine coverage on contract for its participants. FQHCs (and other 340B-eligible providers) that are interested in this option should contact the Apexus Answers Call Center at 888.340.BPVP (888.340.2787) or apexusanswers@340Bpvp.com

While Apexus does offer discounts on many vaccines, it is always prudent for FQHCs to contact the manufacturer as well and ask for their best price before finalizing their purchase decisions.

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VETERANS

Background

On June 6, 2018, Congress passed the John S. McCain III, Daniel K. Akaka, and Samuel R. Johnson Veterans Administration Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018, or the VA MISSION Act[29]. Among other provisions, the MISSION Act permits eligible veterans (those who normally receive their care from VA providers) to receive urgent care from non-VA providers. If the non-VA provider has a contract with the VA, the VA will reimburse them for the care, generally at standard Medicare rates.

On June 5, 2019, the VA issued a Final Regulation implementing the urgent care provisions of the MISSION Act, and they went into effect the following day. This Final Rule stated that the VA considers receiving an influenza shot to be urgent care, and therefore will reimburse non-VA providers for giving influenza vaccines to qualified veterans (provided that they have a contract with the VA).[30] The Final Rule also stated that – unlike some other types of urgent care visits – veterans will never be charged a copay for influenza vaccine-only visits with non-VA providers. Note that this provision is limited to influenza vaccination, and does not include other types of adult vaccination.

Strategy to increase adult vaccination rates among eligible veterans

Health centers can reach out to veterans who normally receive their care through VA providers to offer them influenza immunizations. Health centers that have a contract with the VA will be reimbursed at prevailing Medicare rates for this service, and the veteran will not be charged a copay.

CONCLUSION

While there are many perceived policy-related barriers to FQHCs' ability to access, be reimbursed for, and ultimately administer adult immunizations, by exploring and taking action on low-lift, high-yield strategies, FQHCs and the associations that represent them could lower many of those barriers. Strong partnerships in this work are key; collaboration among PCAs and their FQHC members, health departments, state Medicaid offices, and private/public entities can help to move the needle on many of the strategies mentioned. Once policy is set, interdisciplinary workflows can be developed to streamline and standardize the roles each partner plays, both outside and inside the point-of-service, and ultimately improve access to adult immunizations.

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ENDNOTES

[1] https://www.cdc.gov/vaccines/hcp/adults/for-practice/standards/index.html

[2] http://www.nachc.org/wp-content/uploads/2018/05/Section-330-statute-as-of-March-2018-Clean.pdf

[3] https://bphc.hrsa.gov/programrequirements/compliancemanual/introduction.html

[4] https://www.hrsa.gov/sites/default/files/grants/apply/assistance/Buckets/definitions.pdf

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[6] https://bphc.hrsa.gov/uds/datacenter.aspx?q=d

[7] https://bphc.hrsa.gov/uds/datacenter.aspx?q=t6b&year=2018&state=

[8] https://bphc.hrsa.gov/uds/datacenter.aspx?q=t6a&year=2018&state=

[9] https://bphc.hrsa.gov/sites/default/files/bphc/datareporting/reporting/2018-uds-reporting-manual.pdf

[10] https://bphc.hrsa.gov/qualityimprovement/performancemeasures/qualitycare.html

[11] https://bphc.hrsa.gov/programopportunities/fundingopportunities/quality/index.html

[12] https://www.healthypeople.gov/

[13] This definition also explains why the total number of visits for vaccines reported on UDS can exceed the total number of patients reported, even for vaccines such as influenza which require only a single dose. For example, an individual who comes to an FQHC only for a vaccine would count as a visit but not a patient.

[14] https://www.ncqa.org/wp-content/uploads/2019/02/NCQA-AIS-PRS-Webinar-Slides-Feb-2019.pdf

[15] https://bphc.hrsa.gov/programopportunities/fundingopportunities/quality/index.html

[16] https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/ncapca/associations.html

[17] https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/ncapca/natlagreement.html

[18] Ibid

[19] Ibid

[20] https://bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahcpolicymanualpdf.pdf

[21] FTCA coverage, including for volunteer health professionals, is also available for free clinics. See https://bphc.hrsa gov/ftca/freeclinics/policies.html

[22] Core providers whose face-to-face services always trigger a PPS payment under Medicare and Medicaid include physicians, NPs, PAs, clinical psychologists, and clinical social workers. Some state Medicaid agencies also make PPS payments for face-to-face visits with other provider types.

[23] These FAQs are no longer available online; however, NACHC can provide a copy upon request.

[24] https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/ncapca/associations.html

[25] https://www.cms.gov/center/provider-type/federally-qualified-health-centers-fqhc-center.html

[26] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10914.pdf

[27] http://www.immunize.org/laws/pharm.asp

[28] https://www.apexus.com/

[29] https://missionact.va.gov/

[30] The VA does not consider any other types of adult immunizations to be urgent care.

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