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Compliance Q&A: COVID-19 vaccine and testing mandates, incentives

By Rich Gisonny, Anu Gogna and Ben Lupin

As the COVID-19 pandemic continues, employers are considering whether to require employees to be vaccinated in order to reenter the workplace and whether to offer employees vaccine incentives.

The following Q&As are intended to help employers and group health plan sponsors understand some of the legal issues surrounding COVID-19 vaccine mandates and incentives.

Guidance and rules around COVID-19 vaccinations — including in the employment and group health plan context — are evolving, and employers should consult with legal counsel before implementing any decisions.[1]

Q. Can an employer mandate that employees receive a COVID-19 vaccine to return to the workplace?

Under federal law, an employer may mandate COVID-19 vaccinations subject to **EEOC guidance**. Under that guidance, if an employee refuses to be vaccinated and objects due to disability-related reasons or sincerely held religious beliefs, then the employer must engage in an "interactive process" with the employee and, subject to the "undue hardship" standards, provide the employee with a reasonable accommodation.[2]

The EEOC guidance appears to be limited to mandates for employees *returning to the workplace*. It is not clear whether an employer can legally require employees who only work remotely to be vaccinated.

In a unionized workforce, collective bargaining issues should also be considered. A unionized employer generally cannot impose a vaccine policy unilaterally, since it would likely be considered a mandatory subject of bargaining between the employer and the union. Before adopting such a policy, employers should be prepared to bargain with the union(s), although a union may waive its right to bargain. At least one union has recently sued over an employer's mandatory vaccination policy, maintaining that an employer adopted the policy without proper bargaining.

While federal law generally supports an employment-based mandatory vaccination policy, it is important to note that certain states have enacted or are considering enacting laws that prohibit employers from mandating vaccines or targeting employees who refuse to be vaccinated (see the last Q&A below for more details).

Q. How does the U.S. Food and Drug Administration's (FDA's) emergency use authorization (EUA) for the COVID-19 vaccines affect employer mandates?

The U.S. Department of Justice (DOJ) issued a recent **opinion** stating that employers and other entities are not prohibited from imposing vaccination requirements solely because the vaccine(s) are only available subject to EUA.

In addition, federal courts have ruled that EUA status *did not* prevent a hospital from imposing a mandate as a condition of employment, or a university from requiring vaccination

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[1] Editor's note: On September 9, the White House issued an updated COVID-19 plan. See article on page 6 for more details.

[2] See "**New EEOC guidance on employer COVID-19 vaccine policies, incentives,**" *Insider*, June 2021.

for students, faculty and staff – assuming reasonable accommodations were available to those unable to receive the vaccine for legally protected reasons.

FDA approval of the vaccines should resolve this issue. On August 23, 2021, the FDA granted full approval of the Pfizer-BioNTech COVID-19 vaccine.

Q. Can employers offer incentives for employees to be vaccinated for COVID-19 (outside of a group health plan)?
According to EEOC guidance, employers may offer incentives to employees to voluntarily provide proof of COVID-19 vaccination obtained from a third party (such as a pharmacy, personal health care provider or public clinic). Employers must keep such vaccination information confidential pursuant to the Americans with Disabilities Act (ADA).

However, employers that are *administering COVID-19 vaccines* to their employees (either at the workplace or through an agent) may only offer incentives for employees to be vaccinated if the incentives are "not so substantial as to be coercive." Because COVID-19 vaccinations require employees to answer pre-vaccination disability-related screening questions, the EEOC is concerned that a very large incentive could make employees feel pressured to disclose protected medical information. Because the meaning of "so substantial as to be coercive" is not clearly defined in the guidance, any incentive amount should be discussed with legal counsel.

Q. Can an employer impose a premium surcharge on COVID-19 unvaccinated employees or incentivize COVID-19 vaccinated employees through a group health plan?
An employer may implement a COVID-19 vaccination penalty or reward incentive policy using its group health plan *if it is done through a HIPAA-compliant wellness program.*

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A COVID-19 vaccination surcharge or incentive program could be considered a health-contingent wellness program under HIPAA.

As background, HIPAA prohibits group health plans from charging similarly situated individuals different premiums or contributions, or imposing other cost-sharing requirements, based on a health factor, except through a wellness program.

As a result, any offer of a financial reward in exchange for getting the COVID-19 vaccine – or imposition of a penalty/surcharge for those who don't get the vaccine – must comply with the wellness rules under HIPAA/ACA and, depending on the scope of the vaccinations, EEOC wellness rules under the ADA and the Genetic Information Nondiscrimination Act (GINA).

HIPAA/ACA

A COVID-19 vaccination surcharge or incentive program could be considered a *health-contingent* wellness program under HIPAA. Under HIPAA (as amended by the ACA), the eight "health factors" are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence) and disability. A COVID-19 vaccine would appear to fall within "receipt of health care."

Therefore, an employer would need to meet the requirements for health-contingent activity-only wellness programs. Those requirements are as follows:

- Individuals must have the opportunity to qualify for full reward at least once per year.
- Reward cannot exceed incentive limits (30% of plan cost by tier of coverage if dependents can participate; otherwise, 30% of self-only plan cost; up to 50% for tobacco programs).
- The program must be designed to promote health or prevent disease.
- Notice must be given to employees.
- It must be uniformly available to all similarly situated individuals, with a reasonable alternative standard (RAS) offered.

The RAS could be a COVID-19 testing program (see the next page) or could include required masking and distancing, working from home or attending a COVID-19 vaccine education seminar. The RAS does not have to be the same for all employees but will need to be administered and tracked.

The employer must also determine how the COVID-19 vaccination surcharge (or incentive) interacts with other wellness surcharges/incentives the employer currently offers and how the additional incentive/surcharge will affect the offer of affordable coverage to full-time employees under the ACA employer mandate. This is because the amount of a COVID-19 vaccine surcharge must be added to the employee's required contribution in determining affordability under the ACA's employer mandate rules. For example, a $25 monthly surcharge would increase the employee's required contribution by $25 when determining affordability.

EEOC (ADA and GINA)

If a wellness program provides incentives for disability-related inquiries or requires medical examinations of employees, regardless of whether they are participatory or health-contingent, then the EEOC wellness rules would apply.

However, EEOC guidance states that merely *asking* employees whether they have received a COVID-19 vaccination does *not* constitute a disability-related inquiry for purposes of the ADA. But a medical questionnaire that must be completed before a vaccine is received could be considered a disability-related inquiry subject to the ADA.

The EEOC has not issued final rules on how ADA and GINA apply to wellness programs. However, employers should be aware that rewards/penalties must be reasonable and structured in a way as to *not be perceived as coercive.* Further, according to the EEOC guidance, an incentive *may not* extend to an employee's family members receiving a vaccination administered by the employer or its agent, as that could violate GINA.

Employers considering a COVID-19 vaccine surcharge should discuss this with their legal counsel prior to implementation.

Q. Can an employer amend its group health plan to exclude coverage for COVID-19 related treatment for unvaccinated employees?

To date, there is no definitive guidance on this issue, but it appears that taking such a step is likely to violate HIPAA based on the use of a "health factor" to deny treatment and not treating "similarly situated" employees the same under the group health plan.

In addition, an employer-sponsored group health plan that does not cover COVID-19 treatments for unvaccinated employees may face legal challenges under the ADA (e.g., under recent guidance, "long COVID" may be considered a protected disability). In addition to the compliance concerns that should be discussed with qualified legal counsel, an employer should consider related public and employee relations issues.

[A]n employer-sponsored group health plan that does not cover COVID-19 treatments for unvaccinated employees may face legal challenges under the ADA.

Q. Can an employer require employees to take COVID-19 tests?

Federal laws do not prevent an employer from requiring all employees *physically entering the workplace* to be tested for COVID-19, subject to the reasonable accommodation provisions. In fact, the CDC has issued **guidance** that COVID-19 testing may be incorporated as part of a comprehensive approach to reducing transmission in workplaces.

In addition, under the available guidance, COVID-19 tests would be allowed either as (1) an *accommodation* for a mandatory vaccination requirement, or (2) a *RAS* under a wellness program to impose a premium surcharge.

The frequency of these tests should be discussed with legal counsel in consultation with medical professionals and current CDC guidance.

Q. If an employer requires testing for employees unvaccinated for COVID-19, is the employer (or the employer's group health plan) required to cover the cost of COVID-19 testing?

While current federal guidance requires group health plan coverage for certain COVID-19 testing (for "individualized clinical assessments" regardless of whether an individual is symptomatic or has been exposed), under the same **guidance**, a group health plan would *not* be required to cover testing for "employment purposes" (such as testing as part of a "return to work" program).

While employer-sponsored group health plans are not *required* to cover return-to-work COVID-19 testing, under federal guidance a plan sponsor *may choose* to cover such testing. Several insurance carriers and third-party administrators have interpreted this guidance to mean that employment-based COVID-19 testing generally would not be covered by group health plans. Additional guidance may clarify this issue in the future, but for now, employers that wish to cover return-to-work COVID-19 testing through their group health plan should discuss this with their carrier or third-party administrator.

While a *group health plan* may not be required to cover the costs of COVID-19 tests required of employees as a condition of entering the workplace, the *employer* may be legally required to directly cover the costs of the tests. For example, ADA guidance that pre-dated the COVID-19 pandemic suggests that employers may be obligated to pay the costs of administering mandated medical tests in certain circumstances. Also note that, in certain states, it is our understanding that an employer may be required to pay the testing costs as an employment-related business expense.

Moreover, travel time and test-taking time under a COVID-19 testing program might also be compensable under the Fair Labor Standards Act or state law.

Q. Would any state laws need to be considered when mandating COVID-19 vaccines?

In response to federal guidance, legislation has been introduced in many states to prohibit or restrict private employers from requiring COVID-19 vaccinations as a condition of employment, or from discriminating against employees who refuse to be vaccinated.[3]

To date, different versions of such legislation have reportedly been enacted in five states (Arizona, Florida, Montana, New Hampshire and North Dakota). As a result, even when employers comply with all federal law requirements, it is possible that COVID-19 vaccine mandates (or other actions that may be considered work-based discrimination against those refusing to get vaccinated) could be challenged under state (and even local) laws. However, actions taken under the terms of an ERISA-covered self-insured group health plan would allow the employer to argue that ERISA would preempt the applicability and enforceability of those state laws.

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[3] Additional state information on this topic can be found on the National Academy for State Health Policy **webpage.**

Departments issue FAQs delaying health care transparency requirements

By Anu Gogna and Ben Lupin

The departments of Labor, Health and Human Services, and Treasury have released **FAQ guidance** delaying the enforcement of certain requirements under the **Transparency in Coverage Final Rule**[1] and the No Surprises Act (NSA) — part of the Consolidated Appropriations Act (CAA)[2] — "pending further rulemaking."

The departments also announced in the FAQs that they will *not* be issuing regulations for several provisions of the NSA.

Among the guidance, the FAQs provide that:

- No ID card regulations will be issued prior to the effective date of January 1, 2022. In the meantime, the good faith, reasonable interpretation of the law will be in effect.
- No regulations on advanced explanations of benefits (EOBs) will be issued prior to the effective date of January 1, 2022. Enforcement of the requirement is "deferred" until the departments release rulemaking or interim solutions.
- Until regulations or further guidance is issued, the departments strongly encourage plans and issuers to start working to ensure that they can begin reporting the required 2020 and 2021 prescription drug information by *December 27, 2022*.
- While Affordable Care Act grandfathered health plans are *not* subject to the Transparency in Coverage Final Rule, such plans are subject to the NSA and the accompanying transparency rules.

Additional timing and details are listed in the chart on the next page.

[1] See "**Q&A: Final rule on health care transparency**," *Insider*, November 2020

[2] For more information on the CAA's surprise medical billing and transparency requirements, see "**2020 year-end COVID-19 stimulus law: Health and benefit implications**," *Insider*, January 2021.

Updated transparency effective dates

	Original effective date	New effective date	Additional comments
Prescription drug machine readable file (Q&A 1)	January 1, 2022	TBD	Deferred until future rulemaking determines whether the rule is appropriate
In-network rates and out-of-network allowed amounts and billed charges machine readable files (Q&A 2)	January 1, 2022	July 1, 2022	Employers should continue to work with carriers/ third-party administrators to plan to comply
Price comparison tools (Q&A 3)	January 1, 2022 under CAA Phased in from January 1, 2023, to January 1, 2024, under Transparency in Coverage Final Rule	TBD, but not effective before plan years beginning on or after January 1, 2023	To be resolved via future rulemaking
Revision of insurance ID cards (Q&A 4)	January 1, 2022	TBD – No regulations will be issued prior to January 1, 2022	Good faith, reasonable interpretation of the law will be in effect until guidance is issued To be resolved via future rulemaking
Advanced EOBs (Q&A 6)	January 1, 2022	TBD – No regulations will be issued prior to January 1, 2022	To be resolved via future rulemaking
Prohibition on gag clauses on price and quality information (Q&A 7)	December 27, 2020	N/A – Statutory language is self-implementing	Good faith, reasonable interpretation of the law will be in effect until guidance is issued Departments will provide implementation guidance in the future in order to collect attestations starting in 2022
Accuracy of provider directories (Q&A 8)	January 1, 2022	TBD – No regulations will be issued prior to January 1, 2022	Good faith, reasonable interpretation of the law will be in effect until guidance is issued To be resolved via future rulemaking
Balance billing disclosures (Q&A 9)	January 1, 2022	TBD – No regulations will be issued prior to January 1, 2022	Good faith, reasonable interpretation of the law will be in effect until guidance is issued To be resolved via future rulemaking
Continuity of care (Q&A 10)	January 1, 2022	TBD – No regulations will be issued prior to January 1, 2022	Good faith, reasonable interpretation of the law will be in effect until guidance is issued To be resolved via future rulemaking
Reporting of pharmacy benefits and drug costs (Q&A 12)	December 27, 2021	December 27, 2022	Deferred until future rulemaking, but group health plan sponsors are strongly advised to prepare for reporting on 2020/2021 by December 27, 2022

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President Biden's new COVID-19 vaccine plan will affect employers

By Anu Gogna and Ben Lupin

On September 9, the White House issued an updated COVID-19 plan. The **Path Out of the Pandemic** takes a six-pronged approach to fighting the pandemic:

1. Vaccinating the Unvaccinated
2. Further Protecting the Vaccinated
3. Keeping Schools Safely Open
4. Increasing Testing & Requiring Masking
5. Protecting Our Economic Recovery
6. Improving Care for those with COVID-19

Details on implementation will be provided in future regulatory guidance.

The plan will directly affect large employers, with Prong 1 having the most significant impact. Following is a high-level overview of the provisions around vaccinating the unvaccinated:

- **Requiring employers with 100 or more employees to ensure their workers are vaccinated or tested weekly**

  The Department of Labor's Occupational Safety and Health Administration (OSHA) is developing a rule that will require all employers with 100 or more employees to either ensure their workforce is fully vaccinated or require unvaccinated workers to show a negative test result weekly before coming to work. OSHA will issue an Emergency Temporary Standard (ETS) to implement this requirement.

- **Requiring employers with 100 or more employees to provide paid time off to get vaccinated**

  OSHA is developing a rule that will require employers with more than 100 employees to provide paid time off for workers to get vaccinated or to recover post-vaccination. This requirement will be implemented through the ETS.

- **Requiring vaccinations for all federal workers and contractors that do business with the federal government**

  President Biden signed an **Executive Order** on requiring all federal executive branch workers to be vaccinated. The president also signed an **Executive Order** extending this requirement to employees of contractors and subcontractors that do business with the federal government.

OSHA is developing a rule that will require all employers with 100 or more employees to either ensure their workforce is fully vaccinated or require unvaccinated workers to show a negative test result weekly before coming to work.

- **Requiring COVID-19 vaccinations for healthcare workers at Medicare and Medicaid participating hospitals and other healthcare settings**

  The Centers for Medicare & Medicaid Services is acting to require COVID-19 vaccinations for workers in most healthcare settings that receive Medicare or Medicaid reimbursement, including hospitals, dialysis facilities, ambulatory surgical settings and home health agencies.

Employers should continue to monitor developments as they become available and consider taking steps to prepare for implementation.

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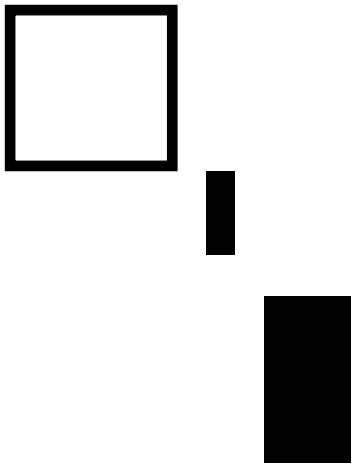

Proposed regulations on air ambulance data reporting requirements

By Maureen Gammon and Kathleen Rosenow

The departments of Health and Human Services (HHS), Labor (DOL) and Treasury, along with the Office of Personnel Management, released **proposed regulations** implementing the air ambulance services reporting requirements under the No Surprises Act (NSA) provisions of the Consolidated Appropriations Act, 2021 (CAA).[1]

These proposed regulations would establish:

- New reporting requirements for group health plans, health insurers and air ambulance service providers on air ambulance services
- New disclosure and reporting requirements on issuers of individual health insurance coverage and short-term, limited-duration insurance regarding agent and broker compensation
- New procedures for enforcement of Public Health Service Act (PHS Act) provisions against providers and facilities, including providers of air ambulance services, and revisions to existing PHS Act enforcement procedures for plans and issuers

The departments also issued a related **fact sheet**.

Comments on the proposed regulations must be received no later than October 18, 2021. The proposed regulations will not take effect until they are finalized. The preamble to the proposed regulations acknowledges that the departments will not have time to issue rules for all CAA provisions before the January 1, 2022 effective date; therefore, group health plans are expected to implement those provisions using a good faith, reasonable interpretation of the statute.

Air ambulance data reporting

Timing

Starting January 1, 2022, NSA protects patients from balance billing by air ambulance providers and requires air ambulance providers, group health plans, health insurers and Federal Employee Health Benefits (FEHB) carriers to submit information and data about air ambulances to federal regulators for calendar years 2022 and 2023.

Comments on the proposed regulations must be received no later than October 18, 2021.

While enforcement of certain other NSA requirements has been delayed,[2] group health plan air ambulance service reporting remains due on March 31, 2023 (for calendar year 2022) and March 30, 2024 (for calendar year 2023).

Reporting entity

Group health plans would submit information to HHS if the plan received claims or made payments for air ambulance services during the reporting period.

Self-insured group health plans, under a written agreement, may have a third-party administrator (TPA) submit the required information to HHS on behalf of the plan, but the plan retains reporting liability.

Health insurers, under a written agreement, may submit the required information for insured group health plans, with the insurer being liable if the information is not submitted.

Air ambulance reporting requirements do not apply to insurers that offer short-term, limited-duration benefits; excepted benefits; individual coverage health reimbursement arrangements; or other account-based plans. However, the reporting requirements do apply to Affordable Care Act grandfathered plans.

Data to be reported

The regulations propose to collect data on air ambulance services furnished within the calendar year as well as those paid for within the calendar year. The information must be submitted to HHS (and the Department of Transportation, in the case of air ambulance providers). HHS, in consultation with the Secretary of Transportation, will issue a public report that summarizes the data and assesses the air ambulance market.

[1] For more information on the NSA's surprise medical billing requirements, see "**2020 year-end COVID-19 stimulus law: Health and benefit implications**," *Insider*, January 2021.

[2] See "**Departments issue FAQs delaying health care transparency requirements**," *Insider*, September 2021.

Under NSA, group health plans and health insurers would be required to submit the following information for air ambulance claims:

- Identifying information for any group health plan, plan sponsor or issuer, and any entity reporting on behalf of the plan or issuer, as applicable
- Market type for the group health plan or health coverage (individual, large group, small group, self-insured plans offered by small employers, self-insured plans offered by large employers and FEHB)
- Date of service
- Billing National Provider Identifier information
- Current Procedural Terminology (CPT) code or Healthcare Common Procedure Coding System (HCPCS) code information
- Transport information, including aircraft type, loaded miles, and pick-up (origin ZIP code) and drop-off (destination ZIP code) locations; whether the transport was emergent or nonemergent; whether the transport was an inter-facility transport; and, to the extent this information is available to the plan or issuer, the service delivery model of the provider (such as government-sponsored [federal, state, county, city/township, other municipal], public-private partnership, tribally operated program in Alaska, hospital-owned or sponsored program, hospital independent partnership [hybrid] program or independent)
- Whether the provider had a contract with the group health plan to furnish air ambulance services under the plan
- Claim adjudication information (including whether the claim was paid, denied or appealed), denial reason and appeal outcome

Employers must prepare to submit the required air ambulance data to HHS by March 31, 2023 (for calendar year 2022) and March 30, 2024 (for calendar year 2023).

- Claim payment information, including submitted charges, amounts paid by each payor and cost-sharing amount, if applicable

Future guidance will provide details on the data submission process.

Going forward

- Employers must prepare to submit the required air ambulance data to HHS by March 31, 2023 (for calendar year 2022) and March 30, 2024 (for calendar year 2023).
- Employers of fully insured group health plans should discuss this requirement with their health insurer and have it in writing that the insurer is responsible for submitting the required information.
- Employers sponsoring self-insured group health plans should consider a written agreement with their TPAs for submitting the required air ambulance services data. Note that TPAs may charge an additional fee for this service, and plans would still maintain the overall responsibility for submitting the information.

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