Avoiding False Claims Act Risks Relating to Federal Funding for Coronavirus (COVID-19) Relief

A Practical Guidance® Practice Note by Matthew D. Jenkins, Hunton Andrews Kurth LLP

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This practice note provides an overview of compliance obligations and False Claims Act risks to healthcare and life sciences companies arising out of three funding streams made available in response to the COVID-19 pandemic: (1) Medicare's Advance Payment Program, (2) the Provider Relief Fund, and (3) the Paycheck Protection Program.

This practice note addresses the following:

- False Claims Act Fundamentals
- COVID-19-Related Federal Funding Streams and Enforcement Trends
- Accelerated and Advance Payment (AAP) Program
- Provider Relief Fund (PRF)
- Paycheck Protection Program (PPP)

False Claims Act Fundamentals

When you advise a healthcare company that receives federal funds about its compliance obligations, a basic understanding of the federal False Claims Act (FCA) is essential.

The FCA imposes civil penalties on persons who knowingly or with reckless disregard:

- Present (or cause others to present) a false or fraudulent claim to the government for payment
- Make or use (or cause others to make or use) a false record or statement material to a false or fraudulent claim for payment from the government
- Make a false or fraudulent claim to wrongfully retain money or property that is owed to the government
- Make or use (or cause others to make or use) a false record or statement material to an obligation to pay or transmit money or property to the government

Reverse FCA liability can attach where a healthcare company wrongfully conceals or improperly avoids or decreases an obligation to pay or transmit money or property to the government. Under the Affordable Care Act, healthcare providers have 60 days to report and return overpayments once they have been identified.

Private whistleblowers (relators) have substantial financial incentives to report false claims to the government, even in cases where the whistleblower may have been involved in bad conduct:

- Relators can bring lawsuits (called qui tam suits) in the name of the federal government, alleging the defendant submitted false claims and share in the recovery of treble damages, civil penalties (roughly $11,000 to $22,000 per claim), plus attorney's fees
- Depending upon the dollar amount of any false claims and the number of claims, qui tam lawsuit recoveries can easily reach millions – if not hundreds of millions of dollars

COVID-19-Related Federal Funding Streams and Enforcement Trends

In response to the COVID-19 pandemic, several federal funding streams were made available to healthcare companies contending with the tandem effects of reduced demand for conventional healthcare services, such as elective surgery cases, and increased demand for healthcare services specific to COVID-19, such as intensive care units, respiratory support technology, and acute care beds.

Although demand for COVID-19-related services was far from uniform across the country, in those locations where the virus hit hardest, hospitals were confronted with the very real possibility of not having enough ventilators, personal protective equipment (PPE), and trained staff to deal with surging demand, at the same time, the hospitals were dealing with substantial reductions in revenue resulting from the cessation of elective caseload. Supporting the ability of providers to secure funding sufficient to remain in operation, acquire additional PPE, and maintain their workforce were thus paramount concerns of the federal government.

The need for immediate and significant federal funding to combat the widespread emergency circumstances brought on by the COVID-19 pandemic means that the government's response will be in the nature of a "pay and chase" approach. This means that the government's funding was not contingent on any level of real compliance review to ensure recipients met whatever requirements attached to receipt of the various streams of federal funding. Rather, the government will rely on certifications of compliance from recipients, audit mechanisms, and strong enforcement actions against those whose certifications were false or fraudulent. And those enforcement actions will be combined with a likely substantial level of private whistleblower actions under the FCA.

Accelerated and Advance Payment (AAP) Program

The Medicare Financial Management Manual (FM Manual) authorizes the issuance of accelerated payments in certain circumstances including "highly exceptional situations where CMS [Centers for Medicare and Medicaid Services] deems an accelerated payment is appropriate." The provider receiving an accelerated payment must meet all eligibility requirements, "including an assurance that recoupment of the payment will be made on a timely basis."

When the COVID-19 pandemic prompted the secretary of the U.S. Department of Health and Human Services (HHS) to declare a public health emergency, CMS expanded its Accelerated (for Part A providers) and Advance (for Part B suppliers) Payment Program. Such payments were made "available to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications." Note that such payments were not grants or awards of federal funding. Absent further action by Congress, AAP program payments must be repaid.

Eligibility Qualifications

The eligibility qualifications listed on CMS' Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID-19 Emergency required the provider/supplier to:

- Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form
- Not be in bankruptcy
- Not be under active medical review or program integrity investigation –and–
- Not have any outstanding delinquent Medicare overpayments

Repayment and Recoupment

Under the expansion announced by CMS, providers and suppliers were able to request up to 100% of the Medicare payment amount for a three-month period, but certain providers were able to request up to six months' payment, and critical access hospitals were permitted to request up to 125% of their payment amount for a six-month period.

Under normal circumstances, the FM Manual requires MACs to attempt recovery of an AAP payment within 90 days after it is issued and authorizes 100% recoupment by withholding of all payments until the debt is paid in full. However, the Continuing Appropriations Act, 2021 and Other Extensions Act (P.L. 116-159), enacted October 1, 2020, amended and substantially extended the repayment terms for all providers that requested and received accelerated and advance payments during the COVID-19 Public Health Emergency. As amended, the repayment terms are as follows:

- Repayment does not begin for one year starting from the date the accelerated or advance payment was issued.
- Beginning at one year from the date the payment was issued and continuing for 11 months, Medicare payments owed to providers and suppliers will be recouped at a rate of 25%.

- After the 11 months end, Medicare payments owed to providers and suppliers will be recouped at the rate of 50% for another six months.
- After the six months end, a letter for any remaining balance of the AAP payment(s) will be issued and providers and suppliers will have 30 days from the date of the letter to pay the balance in full, after which interest will accrue at the rate of 4% from the date of the letter and will be assessed for each full 30-day period that the balance remains unpaid.

Action Steps

Your healthcare provider/supplier clients that requested and received AAP payments during the COVID-19 Public Health Emergency should consider the following action steps:

- Collect and compile copies of documents submitted with any request for AAP payments to confirm eligibility.
- Establish a timeline detailing date(s) for receipt of any AAP payments and identify dates for initiation of recoupment for unpaid balance(s); unless previously repaid in full, recoupment will start on the one year anniversary of payment issuance.
- Monitor correspondence from the MAC and monitor recoupments by the MAC against Medicare payments owed to track and reconcile reduction of outstanding balance(s).
- Pay close attention to any MAC correspondence claiming provider/supplier owes any remaining balance on AAP payments, compare the balance due as claimed by the MAC against internal reconciliation.
- In the event of any repayment discrepancy, immediately notify the MAC in writing (with proof of delivery) providing documentation detailing the discrepancy and proactively address reconciliation to avoid a demand letter and imposition of interest charges.
- Do not use Provider Relief Fund payments (discussed below) to repay payments made under the AAP program.

Provider Relief Fund (PRF)

General and Targeted Distributions

Following enactment of the CARES Act, the Health Resources and Services Administration (HRSA) of HHS initiated a series of general and targeted distributions to disburse $175 billion to be used for healthcare-related expenses or lost revenue due to COVID-19. Phase 1 was a general distribution of $50 billion to Medicare fee-for-service providers allocated in proportion to the providers' share of 2018 patient revenue. Phases 2 and 3 were general distributions of $18 billion and $20 billion, respectively, to eligible providers that applied for funds.

In addition to the three general distributions, PRF payments were made through targeted distributions to specific subsets of Medicare providers (e.g., hospitals in high-impact areas of the COVID-19 pandemic, rural healthcare providers, and skilled nursing facilities). Notably, the Phase 1 PRF payments were distributed without any action on the part of the recipients; HRSA simply distributed funds into the bank accounts used for the administration of Medicare payments to providers.

Much of the guidance from HHS on PRF distributions and the uses of PRF funds has been published to a specific website for the Provider Relief Fund General Information, available at the Provider Relief Fund General Information (FAQs) (the PRFFAQs). HHS frequently updates this website with important guidance from HHS on a range of topics relating to the PRF program, and you should visit it to find the most recent guidance.

Terms and Conditions Applicable to PRF Payments

Unlike AAP payments, PRF distributions were not subject to repayment, assuming providers complied with the Terms and Conditions specific to each such distribution.

Generally, the Terms and Conditions required PRF recipients to certify compliance with eligibility requirements and restrictions on the use of PRF payments. In addition to certifying that PRF payments would "only be used to prevent, prepare for, and respond to coronavirus" and to "reimburse the [r]ecipient only for health care related expenses or lost revenues that are attributable to coronavirus," recipients were also required to certify that PRF payments would not be used "to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse."

Certification and Reporting Obligations for PRF Recipients

The Terms and Conditions imposed reporting obligations as determined necessary by the secretary of HHS (see discussion below regarding Auditing and Reporting Requirements).

Importantly, PRF recipients also were required to certify to the truth, accuracy, and completeness of all information provided or to be provided, and to acknowledge that "any deliberate omission, misrepresentation, or falsification of any information [submitted] . . . may be punishable by criminal, civil, or administrative penalties, including but not limited to revocation of Medicare billing privileges, exclusion from federal health care programs, and/or the imposition of fines, civil damages, and/or imprisonment."

Finally, irrespective of whether a PRF recipient used the attestation portal to sign the Terms and Conditions, recipients that retained PRF payments for at least 90 days without contacting HHS about returning funds were deemed to have accepted such Terms and Conditions.

Use Restrictions on PRF Payments

Despite clear indications of the permitted uses for PRF distributions that included "lost revenue due to COVID-19," on September 19, 2020, HRSA issued a Post-Payment Notice of Reporting Requirements tightening the use restrictions applicable to PRF distributions by changing the method for reporting lost revenue into one requiring providers to demonstrate "a negative change in year-over-year net patient care operating income." HRSA did so believing that it should prohibit providers from using PRF payments to become more profitable than they were pre-COVID-19. That approach provoked widespread opposition and on October 22, 2020, HRSA issued amended PRF reporting instructions, which abandoned the more narrow use restrictions tied to lost profits. HRSA's amended reporting instructions "provide for the full applicability [of] PRF distributions to lost revenues."

As amended, the General and Targeted Distribution Post-Payment Notice of Reporting Requirements specify the four areas of data elements that PRF recipients will be required to report to allow HRSA and HHS to determine "whether recipients properly used PRF payments, consistent with the Terms & Conditions associated with payment." Those areas include demographic information, expenses attributable to COVID-19 not reimbursed by other sources, lost revenues attributable to COVID-19, and additional nonfinancial data (e.g., facility, staffing and patient care, and change in ownership).

Precisely what uses of PRF funds will be regarded as proper are addressed in the "Use of Funds" section of the PRFFAQs. The majority of the PRFFAQs regarding use of funds were added on October 28, 2020, except for one added on November 2, 2020, and several more on November 18, 2020, relating to expenses for capital facilities and equipment. The PRFFAQs on use of funds address a wide range of expenditures (e.g., salaries and fringe benefits for different categories of staff, allocation of parent overhead costs, depreciation, etc.) as well as calculation methods for reporting various data items. Therefore, in advising clients on how to meet their reporting obligations, you should consult the PRFFAQs website for specific guidance and to be sure that the latest instructions from HHS are considered.

In the Paycheck Protection Program and Healthcare Enhancement Act, Pub. Law No. 116-139, Congress specified the funds appropriated for a "Public Health and Social Services Emergency Fund" could be used "to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers **for health care related expenses or lost revenues** that are attributable to coronavirus" subject to the proviso that "these funds may not be used to reimburse **expenses or losses** that have been reimbursed from other sources or that other sources are obligated to reimburse." (emphasis added)

The language used by Congress describes two categories of use for PRF funds: (1) healthcare related expenses, and (2) lost revenues. In theory, providers could experience either or both categories as a consequence of COVID-19.

A provider treating substantial numbers of COVID-19 patients might have incurred substantially higher expenses in treating those patients because of the need to acquire additional PPE. Such expenses, provided they were not reimbursed from other sources, could be reimbursed with PRF funds.

Alternatively, a provider could have experienced a substantial reduction in revenues due to cancelled elective surgeries—those lost revenues, provided they were not reimbursed from other sources, could be reimbursed with PRF funds.

Finally, a provider could experience both increased healthcare related expenses for treating COVID-19 patients and lost revenues due to the cancellation of cases unrelated to COVID-19. In such case, provided such expenses or losses were not reimbursed from other sources or that other sources were not obligated to reimburse such expenses or losses, they could be reimbursed by PRF funds. One of the key use restrictions is that PRF payments may not be used "**to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse**." (emphasis added) According to guidance published by HHS, this means that once a provider has identified "healthcare related expenses attributable to coronavirus" (the category of expenses to which PRF payments may be applied), the provider must next "apply any amounts received through other sources, such as direct patient billing, commercial insurance, Medicare/Medicaid/Children's Health Insurance Program (CHIP), or other funds received from the Federal Emergency Management Authority (FEMA), the Provider Relief Fund COVID-19 Claims Reimbursement to Healthcare Providers and Facilities for Testing, Treatment,

and Vaccine Administration for the Uninsured, and the Small Business Administration (SBA) and Department of Treasury's Paycheck Protection Program (PPP) that offset the healthcare related expenses." According to HHS, **only after** those other funding sources have been netted against qualifying expenses can the provider then apply PRF payments against remaining healthcare-related expenses attributable to COVID-19. Note also that HHS requires that netting exercise to include "the other funds **received or anticipated** to offset those expenses." (emphasis added)

Finally, providers holding PRF payments must be alert to the time within which those monies must be used for permissible purposes. Guidance from HHS indicates the funds must be expended no later than June 30, 2021. Unless this deadline is modified, providers will need to determine whether any PRF funds they received have been fully expended for permissible purposes. If not, PRF funds held by the provider starting on July 1, 2021 will likely be viewed as creating an obligation to return those funds within whatever time HHS specifies in future guidance. Because PRF distributions are not payments from the Medicare program, the CMS rule requiring repayment of overpayments within 60 days of identification likely does not apply.

Auditing and Reporting Requirements

Unlike funds typically received by providers from CMS as payment for healthcare services under Medicare, PRF funds are classified by HHS as federal awards and are therefore subject to 45 C.F.R. pt. 75, which establishes uniform administrative requirements, cost principles, and audit requirements for federal awards to non-federal entities. The Governmental Audit Quality Center (GAQC) of the American Institute of Certified Public Accountants (AICPA) maintains a summary of uniform guidance (UG) applicability for new COVID-19-related federal programs. As of November 19, 2020, the GAQC's summary expects that the UG will apply to nonfederal entities (including non-profits) as well as for-profit entities receiving PRF payments and that the PRF program will be subject to single audit requirements as provided in 45. C.F.R. pt. 75.

Note, however, that final authoritative guidance on the single audit requirements will be stated in the Office of Management and Budget's (OMB) 2020 OMB Compliance Supplement Addendum. According to OMB, that addendum will be posted to the OMB Management website, and you should visit the website to determine whether the addendum has been issued.

Detailed discussion of single audit requirements is beyond the scope of this practice note. However, for many entities, the receipt and use of PRF payments may trigger their first experience with the audit requirements applicable to federal awards. You should encourage your healthcare provider clients to determine whether the independent accounting firm they typically rely on for independent audit functions is capable and qualified to perform the type of audit that may be required under 45 C.F.R. pt. 75.

Because much of the technical detail on satisfying the reporting requirements is to be found in the PRFFAQs that HHS continues to update, in advising clients on how to meet their reporting obligations, you should consult the PRFFAQs website for specific guidance and to be sure that you consider the latest instructions from HHS.

- The PRFFAQs acknowledge providers will have "a limited opportunity to submit corrected data for up to 5 business days after the submission deadline," but HHS will only accept corrections "accompanied by a justification for why the provider erred in the initial data submission."
- Data submissions will be regarded by HHS (or qui tam relators under the FCA) as records or statements material to the government's determination on whether PRF funds must be repaid. Providers should exercise extraordinary care in fulfilling their reporting obligations.
- Bear in mind the difference between recoupment (which applies to AAP payments) and return. One PRFFAQ, modified on November 5, 2020, addresses whether "HHS intend[s] to recoup any payments made to providers not tied to specific claims for reimbursement, such as the General or Targeted Distribution payments." While HHS reserves the right to audit and collect through recoupment "any Relief Fund amounts that were made in error or exceed lost revenue or increased expenses due to COVID-19," this PRFFAQ states that PRF "payment amounts that have not been fully expended on the combination of healthcare expenses and lost revenues attributable to coronavirus by the end of the final reporting period, **must be returned** to HHS." (emphasis added) Accordingly, providers holding excess PRF payments would be well advised to carefully monitor HHS guidance as to how excess PRF payments are to be returned to determine if affirmative steps are required on their part, as opposed to awaiting recoupment by HHS.
- Now that several pharmaceutical manufacturers have announced the development of highly effective COVID-19 vaccines, providers should carefully track the use of PRF payments used to support the distribution of

vaccines licensed or approved by the federal Food and Drug Administration, as such uses qualify (including funds used to purchase additional refrigerators, personnel costs to administer vaccinations, and payments for vaccine doses).

- PRF payments may not be used to repay amounts due back to CMS under the Accelerated and Advance Payment program.

Paycheck Protection Program (PPP)

Although not specific to the healthcare setting, Congress established the Paycheck Protection Program as yet another stream of federal assistance available to entities affected by the economic disruptions brought on by COVID-19. PPP loans were made to enable loan recipients to sustain payroll, or to cover eligible business mortgage interest costs, eligible business rent or lease costs, and eligible business utility costs. In short, PPP loans were intended to address revenue shortfalls that could impair the ability of a business to survive if it could not keep its workforce, or pay its occupancy costs or utility costs.

The PRFFAQs address PPP loan proceeds by noting that "[t] here is no direct ban under the CARES Act on accepting a payment from the Provider Relief Fund and other sources, so long as the payment from the Provider Relief Fund is used only for permissible purposes and the recipient complies with the [PRF] Terms and Conditions." This means that if you have a client that received both PRF payments and PPP loan proceeds, they will have to include PPP loan proceeds in meeting their PRF reporting requirements.

Guidance from HHS suggests that PPP loan proceeds would be netted against healthcare expenses attributable to COVID-19. But the costs that PPP loans were intended to cover (i.e., existing employee salaries) are routine expenses a provider would expect to incur in the normal course of business. Such costs likely are not healthcare-related expenses that are attributable to COVID-19 because the provider would have incurred them regardless; they are not incremental expenses incurred because of COVID-19. So requiring a provider to net PPP loan proceeds against healthcare expenses attributable to COVID-19 would seem to require a use of PPP loan proceeds for a purpose other than that for which they were advanced.

On the other hand, PPP loan proceeds were intended to allow businesses that had lost revenues to continue making payments for payroll, rent, mortgage interest, and utility bills. Therefore, including PPP loan proceeds in determining lost revenues would be consistent with the directive from Congress that PRF funds not be used to reimburse lost revenues that were reimbursed from other sources. In practical terms, this means that a provider that received PPP loan proceeds should not be required to net those proceeds against healthcare related expenses attributable to COVID-19 and should be able to use PRF funds to reimburse such expenses absent other sources of reimbursement. However, a provider that received PPP loan proceeds would have to net those proceeds in calculating lost revenues.

Advising healthcare companies on their compliance obligations with respect to federal funding relating to the COVID-19 pandemic requires careful attention to the evolving guidance that is being issued by HHS through its website. You must focus on the particular funding streams under which a client healthcare company may have received federal funds. The use restrictions, reporting obligations, repayment terms, and other program elements differ, in some cases significantly, across the funding streams discussed in this practice note. A one-size-fits-all approach is not sufficient. The Terms and Conditions applicable to each funding source must be satisfied with respect to the specific funds received from such source.

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Matt chaired the ABA Health Law Section's Task Force on Accountable Care Organizations. He also chaired the ABA Health Law Section's Business Transactions Interest Group and the Health Law Section of the Virginia State Bar.

- Negotiated sales of and secured regulatory approvals for multiple acute care hospital acquisitions. Transactions have included not-for-profit hospitals affiliating with other not-for-profit systems as well as conversions of not-for-profit hospitals through lease or purchase transactions to for-profit status.
- Represented large multi-hospital systems in numerous government investigations of alleged billing violations, negotiating settlements with governmental enforcement authorities.
- Represented large multi-hospital systems in numerous joint ventures with other institutional providers and physicians.
- Advised several multi-hospital systems on restructurings and disposition of asset transactions.
- Secured state attorneys general approval for multiple transactions involving acquisition or disposition of charitable assets.
- Negotiated third-party payor/provider contracts for multi-hospital systems and sole community hospitals.
- Regularly advises health care clients on compliance matters (Stark, fraud and abuse, licensure, JCAHO, Medicare/Medicaid) involving hospital operations, provider joint ventures, hospital-physician transactions and patient care.
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