2020 Legal Update: All Things COVID-19

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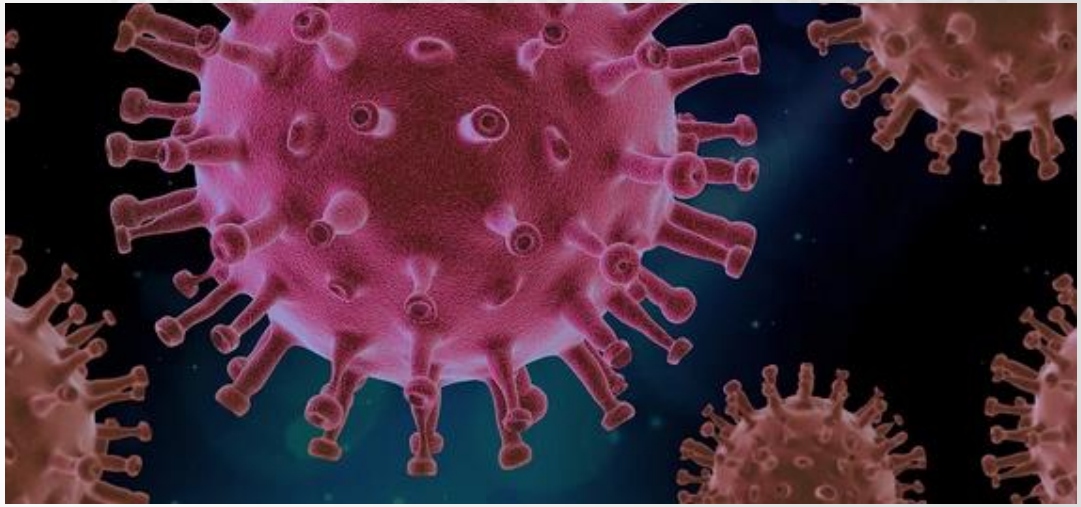

Agenda

1. Current Landscape
2. Accelerated/Advanced Payments
3. The Provider Relief Fund
4. Stark Law Blanket Waivers
5. OIG Waivers/FAQs
6. CMS Waivers and Flexibilities
7. Suggestions if a Provider Tests Positive for COVID-19
8. COVID-19 Patients: Best Practices
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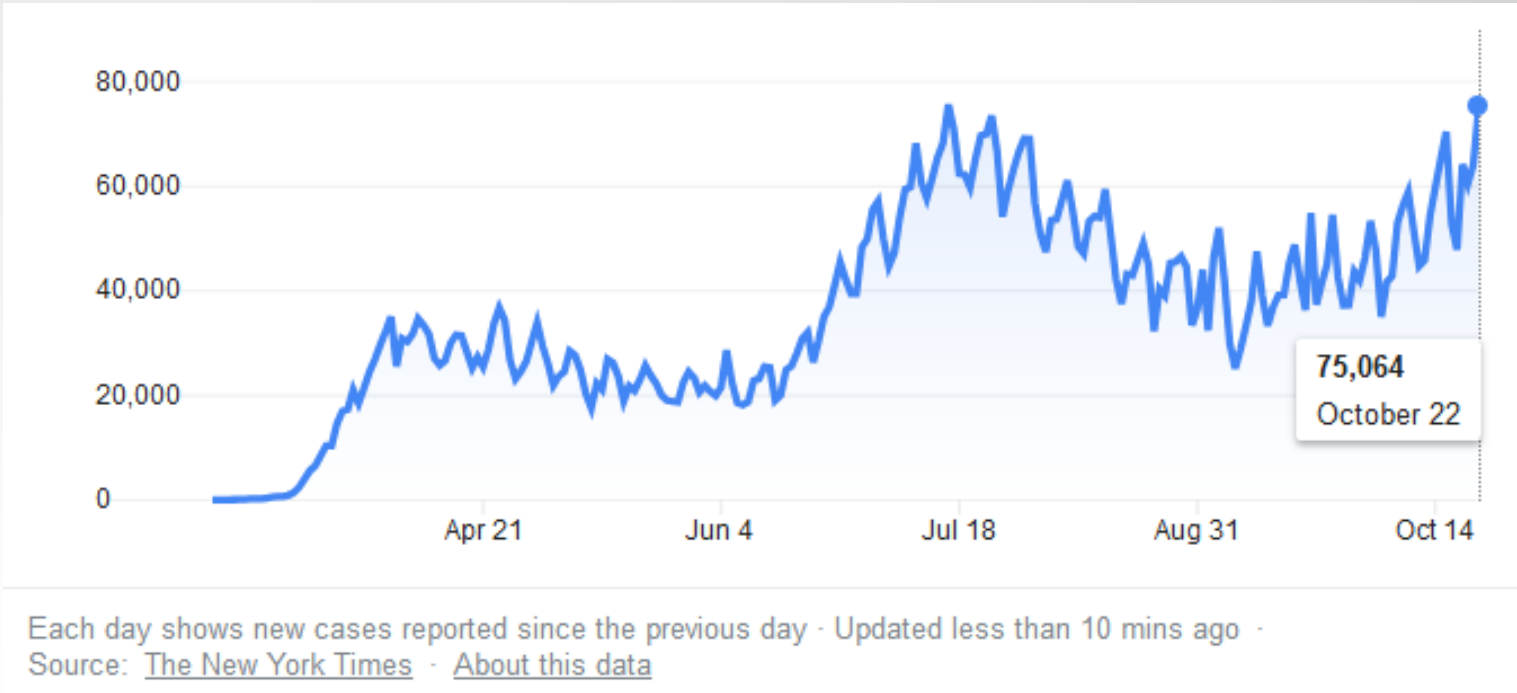
1. Current COVID Landscape

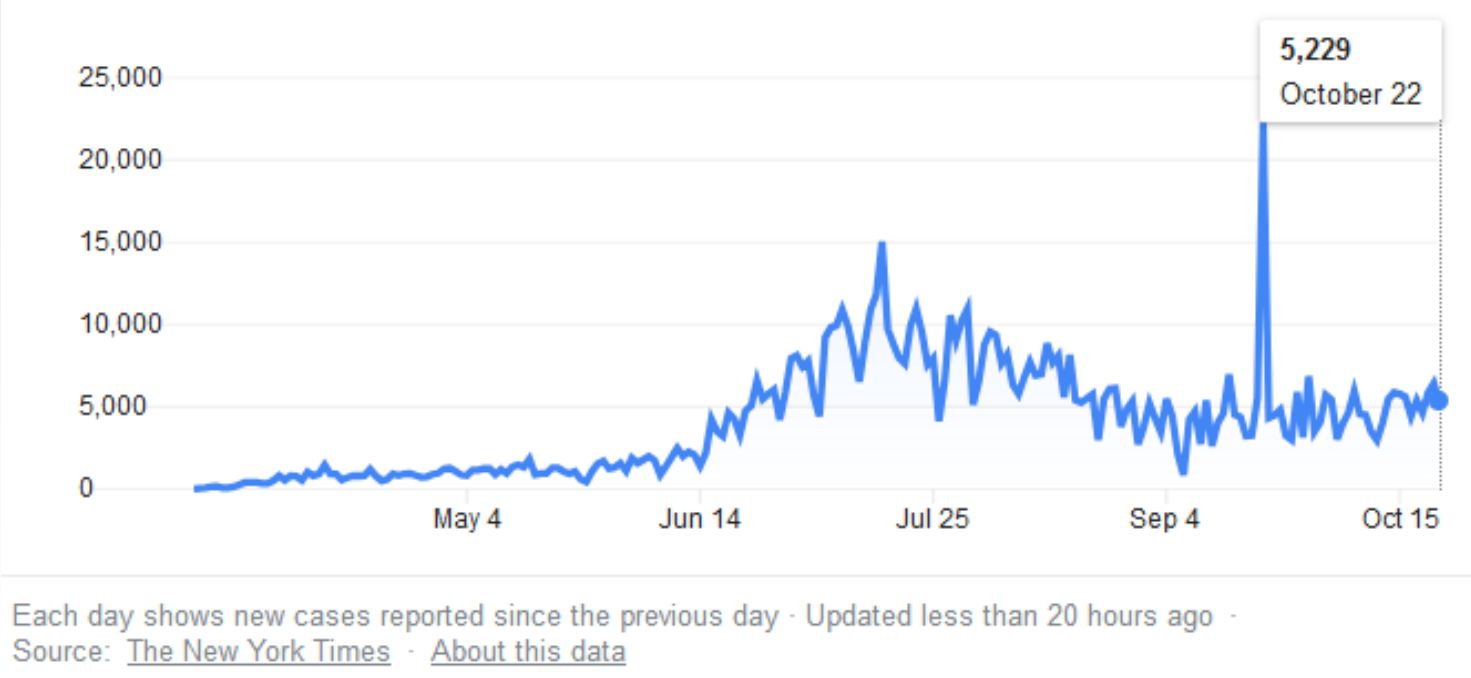
Current Landscape

Total U.S. COVID-19 Cases



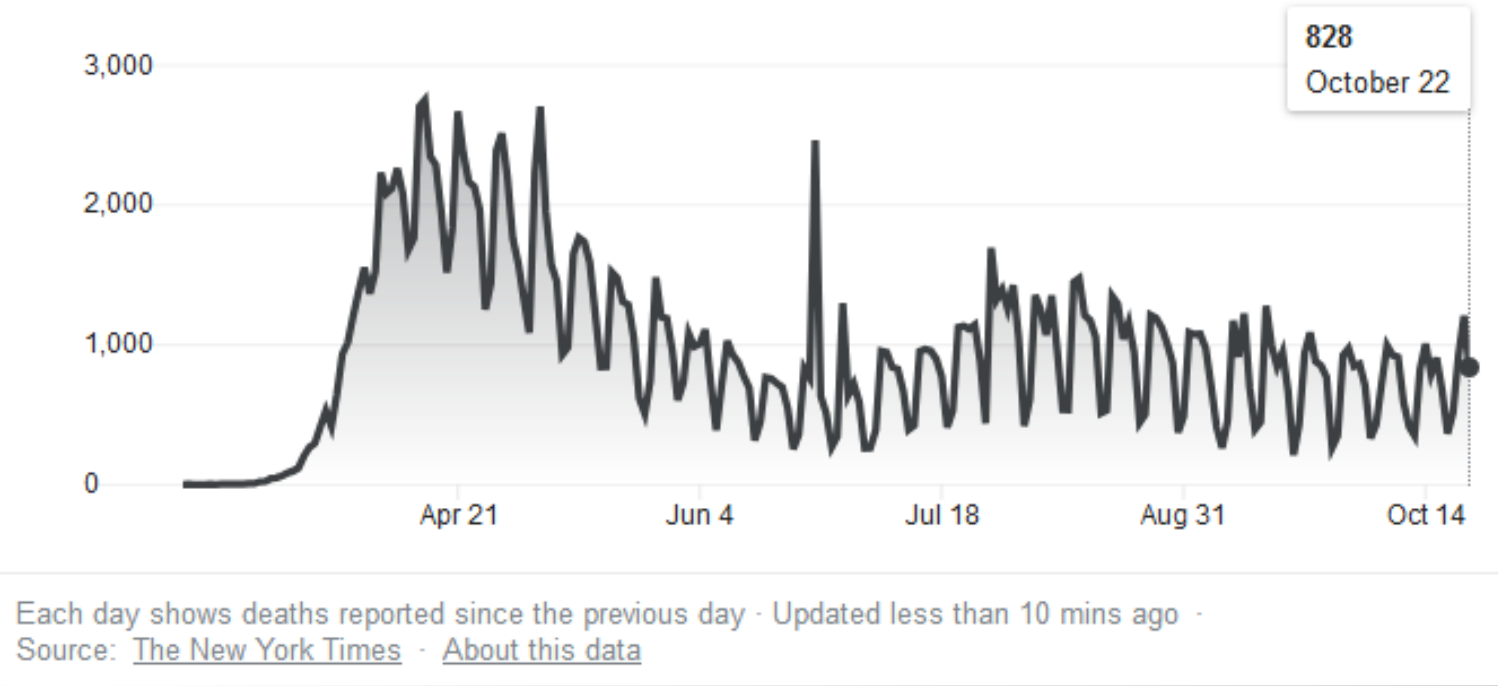
Current Landscape

Total COVID-19 Cases in Texas



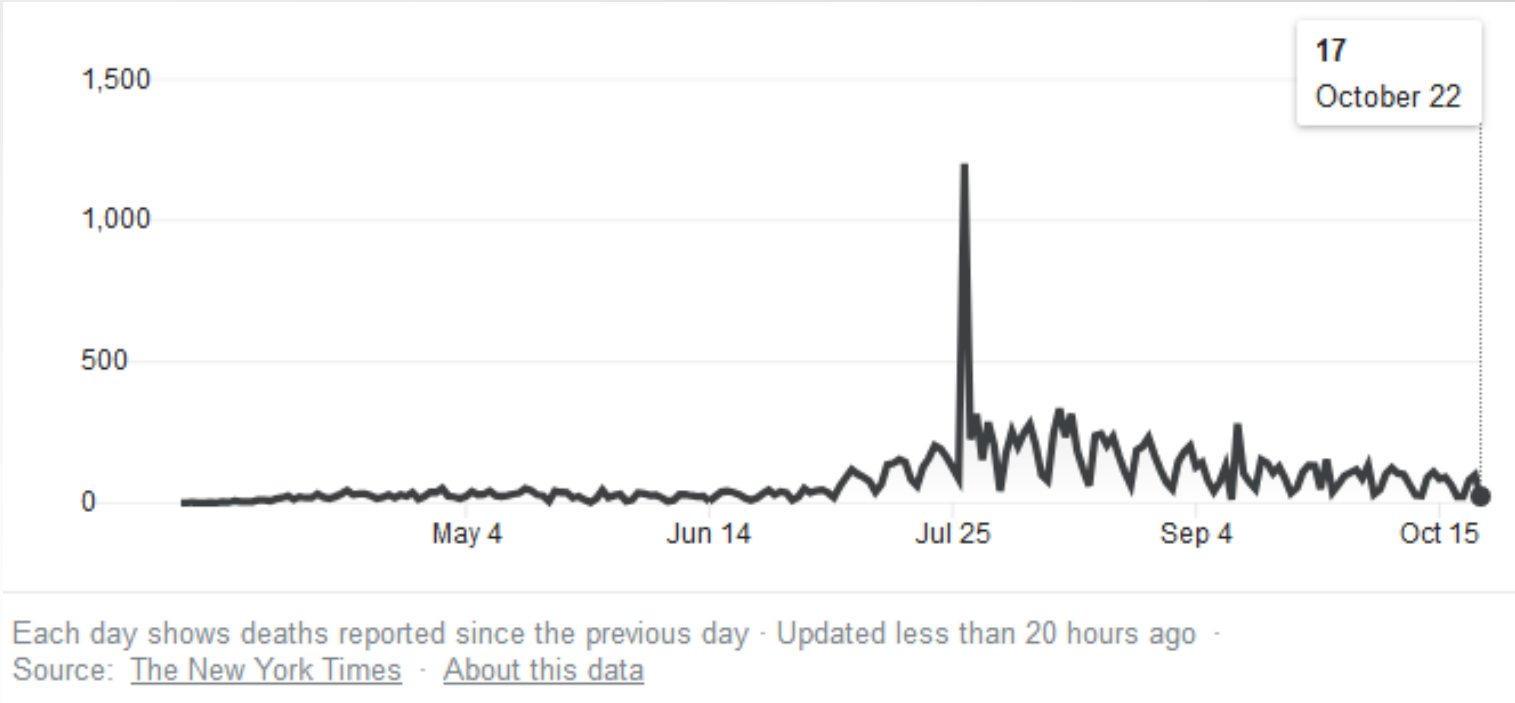
Current Landscape

Total U.S. COVID-19 Deaths



Current Landscape

Total COVID-19 Deaths in Texas



2. Accelerated/Advance Payments

CMS' Relief for Medicare Providers

Accelerated and Advance Payment Loans

- WHO: Medicare Part A or Part B providers or suppliers had the opportunity to request accelerated or advance payments through the applicable Medicare Administrative Contractor's ("MAC") website.
- WHEN: Originally, providers would have started repaying these loans in August 2020. But, the Continuing Appropriations Act, 2021 and Other Extensions Act (H.R. 8337) (enacted in October), provided recipients of accelerated and advance payments one year from the first loan payment to begin repayments.

CMS' Relief for Medicare Providers

Accelerated and Advance Payment Loans

- **HOW**: Every claim submitted by the provider or supplier will be offset to repay the accelerated or advance payment. The process is automatic. If the loans are not paid in full by 29 months after the first payment, an interest rate of 4% will be charged.
- **FYI**: As of April 26, 2020, CMS ceased accepting any additional applications for the Advance Payment Program, and began reevaluating all pending and new applications. As of October 8, 2020, CMS no longer accepts applications for accelerated or advance payments related to the COVID-19 PHE. The Provider Relief Fund continues to be available to healthcare providers to deal with the COVID-19 response.

3. The Provider Relief Fund

The Provider Relief Fund

Support Under the CARES Act and PPPCHE Act

- **HOW**: The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") and the Paycheck Protection Program and Health Care Enhancement Act ("PPPCHE Act") set aside approximately $175 billion in payments to be distributed through the Provider Relief Fund.

- **WHAT**: These distributions are not loans, meaning healthcare providers will not have to repay any money received from these funds. Healthcare providers accepted certain terms as a condition to keep funds received from the provider relief fund. It is important that providers remain compliant with such terms.

The Provider Relief Fund

April

***April 10 - April 17* First round of Phase 1 General Distribution**
$30 Billion distributed to nearly 320,000 Medicare Fee-For-Service (MFFS) billing providers based on their portion of 2019 MFFS payments

***April 24* Second round of Phase 1 General Distribution**
$9.1 Billion to almost 15,000 Medicare Fee-For-Service billing providers based on revenues from CMS cost report data
$10.9 Billion available to Medicare Fee-For-Service billing providers based on revenue submissions to the provider portal

May

***May 6* Rural Distribution**
$10 Billion to almost 4,000 rural health care providers including hospitals, health clinics, and health centers

***May 7* First round of COVID-19 High-Impact Distribution**
$12 Billion to 395 hospitals that had 100 or more COVID-19 admissions between Jan 1 and Apr 10

***May 22* Allocation for Skilled Nursing Facilities**
$4.9 Billion to over 13,000 certified Skilled Nursing Facilities

***May 29* Allocation for Tribal Hospitals, Clinics, and Urban Health Center**
$500 Million to approximately 300 IHS programs

Image taken from HHS's website

The Provider Relief Fund

June

***June 3* Deadline for Phase 1 General Distribution**
Deadline for providers to submit revenue information and apply for a portion of the additional $20 Billion General Distribution (Phase 1)

***June 9* Phase 2 General Distribution & Distribution to Safety Net Hospitals**
$15 billion to eligible Medicaid, CHIP, and Dental providers
$10 billion to Safety Net Hospitals

***June 15* Second round of COVID-19 High-Impact Distribution**
Deadline for hospitals to update their number of COVID-19 positive inpatient admissions between January 1, 2020 and June 10, 2020, to qualify for second round of funding.

July

***July 10* Distribution to Safety Net Acute Care Hospitals, Certain Specialty Rural Providers**
$3 billion to hospitals serving vulnerable populations on thin margins
~$1 billion to specialty rural hospitals, urban hospitals with certain rural Medicare designations, and hospitals in small metropolitan areas

***July 17* Second round of COVID-19 High-Impact Distribution**
$10 billion to hospitals with over 161 COVID-19 admissions between January 1 and June 10, 2020, one admission per day, or a disproportionate intensity of COVID admissions

Image taken from HHS's website

The Provider Relief Fund

August

***August 7* Allocation for Nursing Homes**
$2.5 billion to nursing homes mid-August to support increased testing, staffing, and PPE needs

***August 14* Distribution to Certain Children's Hospitals**
HHS to begin distributing $1.4 billion to 80 free-standing children's hospitals

***August 27* Distribution to Nursing Homes**
$2.5 billion to nursing homes to support increased testing, staffing, and PPE needs

September

***September 1* Phase 2 General Distribution for Assisted Living Facilities**
Assisted living facilities (ALFs) may now apply for funding under the Provider Relief Fund Phase 2 General Distribution allocation

***September 3* Nursing Home Incentive Payment Plans**
HHS announces details of $2 billion performance-based incentive payment distribution to nursing homes

October

***October 1* Announcement of Phase 3 General Distribution**
HHS announces $20 billion in new funding for providers on the frontlines of the coronavirus pandemic.

***October 22* HHS Expands Relief Fund Eligibility and Updates Reporting Requirements**
HHS announces broader category eligible providers for Phase 3 General Distribution funding and amends reporting requirements.

Image taken from HHS's website

The Provider Relief Fund

Terms and Conditions

- The Terms and Conditions specific to each distribution are available at: https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html#terms-and-conditions

The Provider Relief Fund

Terms and Conditions Examples – General Distribution

1. Agree not to seek collection of out-of-pocket payments from a COVID-19 patient that are greater than what the patient would have been required to pay if the care was provided by an in-network provider;
2. Certify that they will not use the payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse;
3. Submit reports as the HHS Secretary determines necessary to ensure compliance with the conditions imposed on the payments;
4. Maintain appropriate records and cost documentation, including financial management and record retention and access documentation, and other information required by future program instructions to substantiate the reimbursement of costs under this award; and
5. Fully cooperate in all audits the Secretary, Inspector General, or Pandemic Response Accountability Committee conducts to ensure compliance with the Terms and Conditions.
6. As with other federal funds, the payments may not be used for abortions, and they may not pay for the salary of an individual at a rate in excess of an Executive Level II. In 2020, the salary limitation for Executive Level II is $197,300.
7. Within 45 days of receiving this payment, providers must sign an attestation confirming receipt of the funds and agreeing to the terms and conditions of payment. If a provider receives payment and does not wish to comply with the terms and conditions, the provider must contact HHS within 30 days of receipt of the payment and remit the full payment to HHS, as instructed. Not returning payment within 30 days of receipt will be viewed as acceptance of the Terms and Conditions.

4. Stark Law Blanket Waivers

Stark Blanket Waivers

COVID-19 Purposes

- The blanket waivers apply only to financial relationships and referrals related to the national COVID-19 emergency. Any remuneration described must be directly between the DHS entity and the physician or the physician organization in whose shoes the physician stands, or an immediate family member of the physician. Further, the remuneration and referrals described in the blanket waivers must be solely related to "COVID-19 Purposes," meaning:
  - Diagnosis or the provision of medically necessary treatment of COVID-19 for any patient or individual, whether or not the patient or individual is diagnosed with a confirmed case of COVID-19;
  - Securing the services of physicians and other health care practitioners and professionals to furnish medically necessary patient care services, including services not related to the diagnosis and treatment of COVID-19, in response to the COVID-19 emergency;
  - Ensuring the ability of health care providers to address patient and community needs in response to the COVID-19 emergency;
  - Expanding the capacity of health care providers to address patient and community needs due to the COVID-19 emergency;
  - Shifting the diagnosis and care of patients to appropriate alternative settings due to the COVID-19 emergency; or
  - Addressing medical practice or business interruption due to the COVID-19 emergency to maintain the availability of medical care and related services for patients and the community.

Stark Blanket Waivers

Waivers of Fair Market Value Requirements

- Remuneration above or below the fair market value ("FMV") paid by an entity to a physician for services personally performed by the physician;
- Rental charges below FMV paid by an entity to a physician for the entity's lease of office space from the physician;
- Rental charges below FMV paid by an entity to a physician for the entity's lease of equipment from the physician;
- Remuneration below FMV from an entity to a physician for items or services purchased by the entity from the physician;
- Rental charges below FMV paid by a physician to an entity for the physician's lease of office space from the entity;
- Rental charges below FMV paid by a physician to an entity that are below FMV for the physician's lease of equipment from the entity;
- Remuneration from a physician to an entity that is below FMV for the use of the entity's premises or for items or services purchased by the physician from the entity;
- Remuneration from an entity to a physician resulting from a loan to the entity: (a) with an interest rate below FMV; or (b) on terms that are unavailable from a lender that is not a recipient of the physician's referrals or business generated by the physician; and
- Remuneration from a physician to an entity resulting from a loan to the entity: (a) with an interest rate below FMV; or (b) on terms that are unavailable from a lender that is not in a position to generate business for the physician.

Stark Blanket Waivers

Waivers Related to Incidental Benefits and Non-Monetary Compensation

- Remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceeds the limit set forth in Federal regulations, which is $36 per occurrence for 2020;
- Remuneration from an entity to a physician in the form of nonmonetary compensation that exceeds the limit set forth in Federal regulations, which is $423 per calendar year for 2020;

Waiver Related to Writing and Signature Requirements

- Referrals by a physician to an entity with whom the physician has a compensation arrangement that does not satisfy the writing or signature requirement(s) of an applicable exception but satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers;

Waivers Related to Group Practices

- The referral by a physician in a group practice for medically necessary DHS furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" for purposes of the in-office ancillary services exception to the Stark Law;
- The referral by a physician in a group practice for medically necessary DHS furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes;

Stark Blanket Waivers

Waivers Based on Type of Facility / Location

- The referral by a physician owner of a hospital that temporarily expands its facility capacity above the number of operating rooms, procedure rooms, and beds for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement) without prior application and approval of the expansion of facility capacity as required under the Stark Law;
- Referrals by a physician owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020, provided that: (a) the hospital does not satisfy one or more of the requirements of the referenced Stark Law section; (b) the hospital enrolled in Medicare as a hospital during the period of the public health emergency described; (c) the hospital meets the Medicare conditions of participation and other requirements not waived by CMS during the period of the public health emergency; and (d) the hospital's Medicare enrollment is not inconsistent with the Emergency Preparedness or Pandemic Plan of the State in which it is located;
- The referral by a physician of a Medicare beneficiary for the provision of DHS to a home health agency: (a) that does not qualify as a rural provider; and (b) in which the physician has an ownership or investment interest; and
- The referral by a physician to an entity with which the physician's immediate family member has a financial relationship if the patient who is referred resides in a rural area.

Stark Blanket Waivers

- The blanket waivers do not apply to indirect compensation arrangements as defined in the Stark Law regulations; however, parties may request an individual waiver from CMS. This being said, the Stark Law's "stand in shoes" doctrine may apply, meaning a physician stands in the shoes of his/her physician organization and is deemed to have the same compensation arrangements as the physician organization itself. In such instances, a waiver for indirect compensation may not be necessary.
- Per CMS, sanctions under the Stark Law are waived for referrals and claims that would violate the Stark Law due to a failure of the financial relationship or referral to satisfy the specified requirements of the applicable Stark Law exception. All non-waived requirements of an exception must be satisfied to avoid triggering the prohibitions of the Stark Law.
- Utilizing the blanket waivers, if parties amend the remuneration terms of an existing compensation arrangement during the COVID-19 emergency, the amended arrangement must satisfy all non-waived requirements for the applicable Stark Law exception.
- Upon conclusion of the COVID-19 emergency, the remuneration may be amended once again to return to the original terms or to effectuate additional modifications so long as each time the remuneration terms are amended, all requirements of an applicable Stark Law exception are satisfied, the amended remuneration is determined prior to the amendment, volume or value of referrals or other business generated by the referring physicians is not taken into account and the overall arrangement remains in place for at least one year following the amendment.

Stark Blanket Waivers

- A change to an existing compensation arrangement could potentially be analyzed as an additional compensation arrangement depending on the facts, rather than an amendment to an existing arrangement.
- None of the blanket waivers change the core requirement of the Stark Law exception for physician recruitment previously detailed in a 2007 CMS advisory opinion. In that advisory opinion, CMS opined that a recruitment arrangement should not be amended to provide for additional compensation to the recruited physician because the physician would have already relocated his/her medical practice. Other blanket waivers may be available to assist a physician in order to maintain the availability of care for patients and the community during the COVID-19 emergency depending on the facts of such arrangement.
- Neither the isolated transactions nor fair market value exceptions to the Stark Law require cash payments to satisfy a borrower's debt to a lender. The applicable blanket waivers do not waive sanctions for referrals and claims related to loan repayment, nor the commercial reasonableness requirement. Importantly, the aggregate, value of in-kind payments must be consistent with the amount of the loan balance reduced by in-kind payments. Appropriate repayment terms agreed to prior to the termination of the blanket waivers may continue without violating the Stark Law. Any disbursement of loan proceeds or additional remuneration after termination of the blanket waivers for office space, equipment or services furnished by or to an entity or physician must satisfy all requirements of an applicable Stark Law exception.

5. OIG Waivers/FAQs

Anti-Kickback Statute Guidance

- The OIG noted in a Policy Statement that it will not impose administrative sanctions under the Anti-Kickback Statute for certain remuneration related to COVID-19 blanket waivers of the Stark Law (previous Section).
- As of April 3, 2020 and through termination of the Blanket Waivers, the OIG will not impose administrative sanctions under the Anti-Kickback Statute with respect to remuneration that is covered by the Blanket Waivers which focus on waiving certain fair market value requirements for COVID-19 focused arrangements.
- All conditions and definitions that apply to the Blanket Waivers apply to the OIG Policy Statement.
- OIG has provided additional guidance through FAQs.

Anti-Kickback Statute and Civil Monetary Penalties Guidance

Can an oncology group provide free in-kind local transportation to and from an established patient's house to an alternate practice location for the purpose of receiving medically necessary oncology care?

Because the COVID-19 pandemic presents unique circumstances, OIG believes that free modest, in-kind transportation assistance provided to established patients of an oncology practice would present a low risk of fraud and abuse so long as the transportation assistance is: (a) provided by an "eligible entity" to an "established patient," for free or at a reduced cost to obtain medically necessary items or services furnished; (b) provided only when necessary; and (c) not air, luxury, or ambulance-level transportation. Furthermore, for the transportation assistance to present a low risk of fraud and abuse, the eligible entity must not: (i) determine eligibility for transportation assistance in a manner related to the past or anticipated volume or value of Federal health care program business; (ii) publicly market or advertise the in-kind transportation or market health care items and services during the course of the transportation or at any time by drivers; or (iii) pay drivers or others arranging for the transportation on a per-beneficiary-transported basis.

Anti-Kickback Statute and Civil Monetary Penalties Guidance

Can a clinical laboratory that bills Federal health care programs for laboratory tests to diagnose COVID-19 pay a retail pharmacy a fair market value fee for certain costs that the retail pharmacy incurs related to COVID-19 testing collection sites?

In the context of the COVID-19 public health emergency, the arrangement described in the above question would present sufficiently low risk under the following circumstances: (a) costs are incurred by the retail pharmacy to operate the testing collection sites; (b) payment is fair market value for the items and services furnished by the retail pharmacy in operating the sites; and (c) the retail pharmacy is not submitting claims to Federal health care programs or receiving other Federal or State funding that reimburses it for the items and services furnished by the retail pharmacy in running the sites for which the laboratory reimburses the pharmacy. On the other hand, if the pharmacy billed Federal health care programs for or received Federal or State funding to cover the costs associated with the items and activities for which the clinical laboratory would reimburse the pharmacy, such remuneration may violate the AKS. Further, the parties must determine what the fair market value payment would be for such services.

Anti-Kickback Statute and Civil Monetary Penalties Guidance

Can health care providers furnish services for free or at reduced rates to assist skilled nursing facilities or long-term-care providers that are facing staffing shortages due to the COVID-19 pandemic?

Due to the COVID-19 pandemic, the scenario presented by the above question may present a low risk of fraud and abuse under the AKS and CMP, provided the services are: (a) necessary as a result of staffing shortages connected to the COVID-19 outbreak to meet patient care needs; (b) provided for free or at a reduced cost only when necessary; (c) limited to the period subject to the COVID-19 public health emergency declaration; and (d) not contingent on referrals for any items or services that may be reimbursable in whole or in part by a Federal health care program.

Can a hospital provide for free access to its HIPAA-compliant, web-based telehealth platform to independent contractors on the medical staff to furnish medically necessary telehealth services?

OIG stated that free access to a hospital's telehealth platform by physicians on its medical staff would present a low risk of fraud and abuse under the AKS and could improve beneficiaries' access to telehealth services, provided the platform is: (a) given for free to physicians to furnish medically necessary telehealth services; (b) furnished only when necessary and during the period subject to the COVID-19 public health emergency declaration; (c) not conditioned on the physician's past or anticipated volume or value of referrals to, or other business generated for, the hospital for any items or services that may be reimbursable in whole or in part by a Federal health care program; and (d) offered on an equal basis to all physicians on the medical staff.

6. CMS Waivers and Flexibilities

Telehealth and Diagnostic Testing

Telehealth in Medicare continues to expand

- CMS is waiving the video requirement for telephone evaluation and management services, and behavioral health counseling and educational services, and adding such services to the list of Medicare telehealth services. Medicare beneficiaries will be able to use an audio-only telephone to receive these services.
- For the duration of the COVID-19 public health emergency, CMS is waiving limitations on the types of practitioners that can furnish Medicare telehealth services, so other practitioners including physical therapists, occupational therapists and speech language pathologists may provide telehealth services.
- CMS may add new services to the list of Medicare services that may be furnished via telehealth on a sub-regulatory basis, considering requests by practitioners learning to use telehealth as broadly as possible.

Medicare and Medicaid beneficiaries may more easily receive COVID-19 diagnostic testing

- Originally, CMS said it no longer required an order from a treating physician or other practitioner for COVID-19 tests and certain laboratory tests required to diagnose COVID-19. Moving forward, Medicare will cover a beneficiary's first COVID-19 test without an order, but subsequent tests will require a physician's or other practitioner's order.
- CMS will pay practitioners to assess beneficiaries and collect laboratory samples for COVID-19 tests.
- Medicare will pay for COVID-19 tests performed by pharmacists as part of a Medicare-enrolled laboratory. Medicare will cover certain FDA-authorized COVID-19 serology tests.

Health Care Workforce, and Medicare Shared Savings Program

Actions to augment the healthcare workforce continue

- Physical and occupational therapists may delegate maintenance therapy services to physical and occupational therapy assistants in outpatient settings.

Changes to the Medicare Shared Savings Program

- CMS is adjusting the financial methodology for determining shared savings and shared losses to account for COVID-19 costs so that accountable care organizations ("ACOs") will be treated equitably no matter the extent to which the ACO's patient populations are affected by the COVID-19 public health emergency.
- There will not be an application cycle for 2021. Instead, ACOs whose participation will end at the PY 2020, will be given the option to extend for PY 2021.
- If an ACO is required to increase their financial risk over the course of their current agreement period, those ACOs will have the option to freeze their current risk level for PY 2021 rather than advancing to next risk level.

7. Suggestions if a Provider Tests Positive for COVID-19

CDC COVID-19 Considerations

Preventing the Spread of COVID-19

- The Centers for Disease Control ("CDC") recommends a conservative approach to Health Care Personnel ("HCP") monitoring and implementation of work restrictions. Occupational health programs should have a low threshold for evaluating symptoms and testing HCP.
- The feasibility of contact tracing of exposed HCP and application of work restrictions depends upon the degree of community transmission of SARS-CoV-2 and the resources available for contact tracing:

Community Transmission	Approach
Minimal to no community transmission of SARS-CoV-2	Sufficient resources for contact tracing, and no staffing shortages, risk assessment of exposed HCP and application of work restrictions may be feasible and effective
Moderate to substantial community transmission of SARS-CoV-2	Insufficient resources for contact tracing, or staffing shortages, risk assessment of exposed HCP and application of work restrictions may not be possible. Consider forgoing formal contact tracing and work restriction for HCP with exposures in favor of universally applied screening and source control strategies.

Potential HCP COVID-19 Exposures

Exposure	Personal Protective Equipment Used	Work Restrictions
HCP who had prolonged close contact with a patient, visitor, or HCP with confirmed COVID-19	• HCP not wearing a respirator or facemask • HCP not wearing eye protection if the person with COVID-19 was not wearing a cloth face covering or facemask • HCP not wearing all recommended PPE (i.e. gown, gloves, eye protection, respirator) while performing an aerosol-generating procedure	• Exclude from work for 14 days after last exposure • Advise HCP to monitor themselves for fever or symptoms consistent with COVID-19 • Any HCP who develop fever or symptoms consistent with COVID-19 should immediately contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.
HCP other than those with exposure risk described above	N/A	• No work restrictions • Follow all recommended infection prevention and control practices, including wearing a facemask for source control while at work, monitoring themselves for fever or symptoms consistent with COVID-19 and not reporting to work when ill, and undergoing active screening for fever or symptoms consistent with COVID-19 at the beginning of their shift. • Any HCP who develop fever or symptoms consistent with COVID-19 should immediately self-isolate and contact their established point of contact to arrange for medical evaluation and testing.

Information taken from the CDC, available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Potential HCP COVID-19 Exposures

Definitions

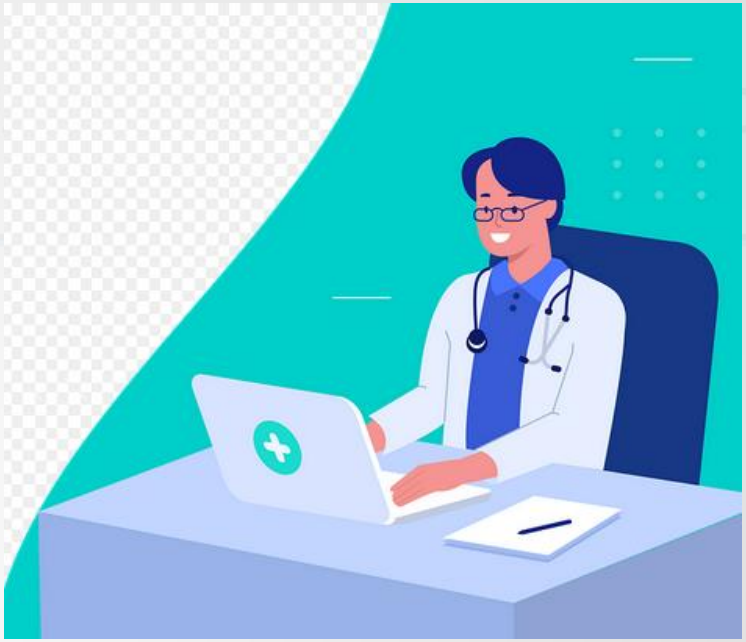
- **HIGH RISK**: Exposure of HCP eyes, nose, or mouth to material potentially containing SARS-CoV-2, particularly if these HCP were present in the room for an aerosol-generating procedure. Other exposures not included as high risk, including having body contact with the patient (e.g., rolling the patient) without gown or gloves, may impart some risk for transmission, particularly if hand hygiene is not performed and HCP then touch their eyes, nose, or mouth. The specific factors associated with these exposures should be evaluated on a case by case basis. Interventions, including restriction from work, can be applied if risk for transmission is deemed substantial.
- **PROLONGED EXPOSURE**: (a) Exposures of 15 minutes or more or (b) any duration if the exposure occurred during performance of an aerosol generating procedure.
- **CLOSE CONTACT**: (a) being within six (6) feet of a person with confirmed COVID-19 or (b) having unprotected direct contact with infectious secretions or excretions of the person with confirmed COVID-19.

Potential HCP COVID-19 Exposures

Definitions (Cont.)

- INFECTIOUS TIME PERIOD:
  - For individuals with confirmed COVID-19 who developed symptoms, the exposure window is 2 days before symptom onset through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions.
  - Individuals with confirmed COVID-19 who never developed symptoms should be considered potentially infectious beginning two (2) days after their exposure until they meet criteria for discontinuing Transmission-Based Precautions. If the date of exposure cannot be determined, using a cutoff of 2 days prior to the positive test through the time period when the individual meets criteria for discontinuation of Transmission-Based Precautions is a conservative approach to identify potentially exposed HCP.
- FEVER: Either a measured temperature ≥100.0°F or a subjective fever. Fever may be intermittent or may not be present in some patients, such as those who are elderly, immunosuppressed, or taking certain medications (e.g., NSAIDs), and clinical judgement should be used to guide testing of patients in such situations.
- HCP: HCP include emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, volunteer personnel). HCP does not include clinical laboratory personnel.

8. Patients with COVID-19: Best Practices



Treating COVID-19 Patients

For certain states/regions with no evidence of a rebound that satisfy the Gating Criteria, re-starting care should be done in accordance with the following considerations:

- **Workforce Availability**
  - Staff should routinely screen for symptoms of COVID-19. Persons who are symptomatic should be tested and quarantined. Staff working in non-COVID-19 care zones should not rotate into COVID-19 care zones.
  - Staffing levels must remain adequate to cover potential surges in COVID-19 cases.
- **Facility Considerations**
  - Facilities that make the decision to provide in-person, non-emergent care should create areas of non-COVID-19 care, with steps to reduce risk of COVID-19 exposure and transmission.
  - Administrative and engineering controls should be established to facilitate social distancing.
  - Visitors should be prohibited unless they are necessary for an aspect of patient care.
- **Sanitation Protocols**
  - Facilities should establish a plan for thorough cleaning and disinfection prior to using spaces or facilities for patients with non-COVID-19 care needs.
  - Equipment used for COVID-19 (+) patients should be thoroughly decontaminated, following guidelines from the Centers for Disease Control and Prevention.
- **Testing Capacity**
  - Testing results should be reported to the state health department, as appropriate.

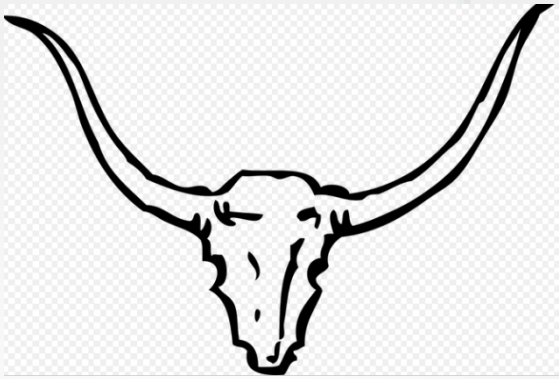
9. COVID-19 Testing

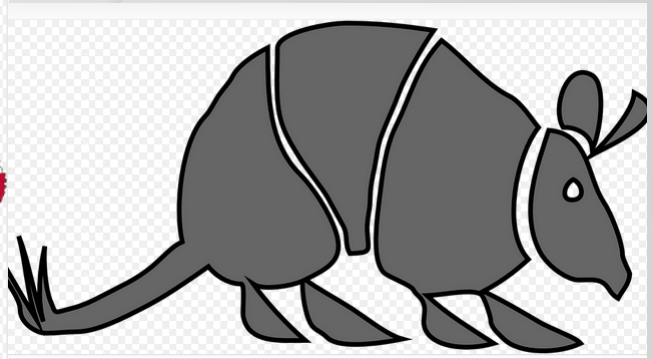
Important Information About COVID-19 Testing

- **Price Transparency**
  - The CARES Act requires providers of diagnostic tests for COVID-19 to post the cash price for a COVID-19 diagnostic test on the provider's public internet website. This pricing transparency requirement was required upon the enactment of the CARES Act and must continue for the duration of the COVID-19 Public Health Emergency.

- **Coverage**
  - Federal law requires most private insurers, Medicare, and Medicaid to cover COVID-19 tests without cost to insured patients. Uninsured patients may receive COVID-19 diagnostic tests for free if their State has opted to extend Medicaid eligibility for such purposes. Additionally, there are resources available to finance free testing for uninsured patients.

10. TMB Guidance





TMB Response to Executive Order GA-19

- In response to Executive Order GA-19, the Texas Medical Board ("TMB") issued an **emergency rule** which went into effect May 1, 2020 at 12:00 a.m. All physicians providing patient care or engaging in an in-person patient encounter must implement the following COVID-19 standards of safe practice:
  - A mask must be worn by the patient and the physician or the physician's delegate when the patient and the physician or the physician's delegate are less than 6-feet apart;
  - All policies the physician, medical and healthcare practice, or facility has in place regarding COVID-19 screening and testing and/or screening patients must be followed;
  - Before any encounter, patients must be screened for potential symptoms of COVID-19 or it must be verified that the patient was previously screened within last 20 days; and
  - Prior to care involving a medical procedure or surgery on the mucous membranes with a high risk of aerosol transmission, a physician or physician's delegate should use N95 masks, or an equivalent protection from aerosolized particles, and face shields.
- All physicians providing patient care or engaging in an in-person patient encounter in medical and healthcare practices, offices, and facilities, other than hospitals, shall post a COVID-19 Minimum Standards of Safe Practice Notice, delineating the minimum standards of safe practice in **each public area and treatment room or area of the office, practice, or facility.**
- Office-based visits can be performed.

TMB Response to Executive Order GA-19

- Masks must be worn when in "proximity of the patient." TMB defines "proximity of the patient" to mean less than a 6-foot distance between the patient and the physician or the physician's delegate. If the physician and patient are not within proximity of each other, then masks do not have to be worn. Doctor offices may set their own policy on mask and glove requirements outside of the patient-physician interaction.
- If a patient does not have a mask, the practice must provide a mask or face-covering. There is not a requirement as to the specific type of mask/face-covering patients must wear. A physician may refuse to treat a patient who is not wearing a mask. The decision to treat a patent is at the discretion of the physician or physician's practice. The patient's mask can be removed if needed during the course of examination or during treatment, a procedure or surgery.
- There may be situations when a patient cannot wear a mask or is incapable of wearing a mask. There may also be certain medical acts or procedures where the wearing of the mask is not feasible as it would impede the medical procedure or act being performed. A practitioner must use the practitioner's own judgment in such situations, utilizing all possible means of safety and taking into account the needs of the patient and the safety of healthcare workers and other patients.
- If a patient cannot wear a mask and the physician choses to deliver care, the practitioner should document the circumstances surrounding such decision.

TMB Response to Executive Order GA-19

Documentation is Key!

- Even though there is not a requirement to document compliance with the emergency rule, TMB strongly recommends it.
- TMB recommends that physicians consider documenting they informed the patient of the measures taken for the patient's safety in the medical record or indicate if a patient is given copies of documents regarding the minimum standards for safe practice.
- For any procedures or surgeries that involve mucous membranes, TMB reminds physicians that the minimum standards for safe practice require specific equipment standards to be utilized.

TMB Response to Executive Order GA-19

Guidance for Chronic Pain Patients

- On June 5, 2020, TMB adopted an emergency rule to help health care professionals provide medical services for chronic pain patients. The treatment of chronic pain with scheduled drugs through telemedicine medical services is prohibited unless:
  - A physician determines that, due to the COVID-19 pandemic, such telemedicine treatment is needed for an established chronic pain patient who seeks telephone refill of an existing prescription or
  - The treatment is otherwise allowed under federal and state law.
- In considering whether to utilize telemedicine medical services for the treatment of chronic pain with controlled substances, the physician should consider factors, including:
  - The date of the patient's last in-person visit,
  - The patient co-morbidities, and
  - Occupational-related COVID-19 risk
- If a patient is treated for chronic pain with scheduled drugs through the use of telemedicine medical services, the patient's medical record must indicate that exception and the reason that a telemedicine visit was conducted.
- The treatment of acute pain with scheduled drugs through the use of telemedicine medical services is allowed, unless otherwise prohibited by law.

Despite the Virus, Enforcement Actions Continue

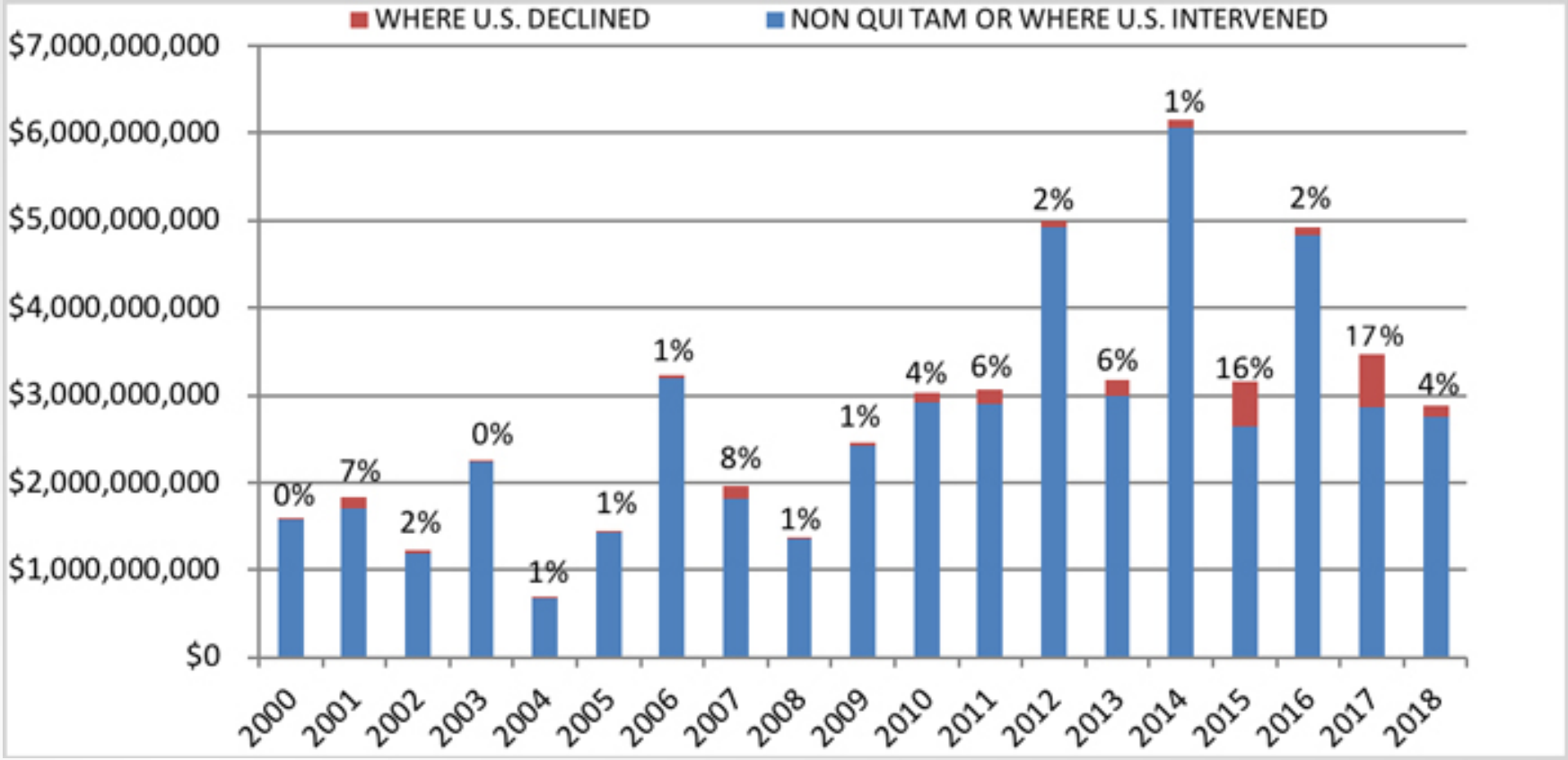
Combating Waste, Fraud, and Abuse in Health Care Remains a Top Federal Priority

- Federal government (DOJ) recovered over $3.054 B in False Claims Act (FCA) cases, with $2.605 B from healthcare cases alone (85% of FCA cases).
- Since 1986, when Congress amended the FCA, DOJ has recovered more than $62 billion under the statute
- 10th consecutive year in FCA recovery exceeding $2.0 billion.
- Gov't paid out $198 M to relators in healthcare *qui tam* cases .
- Direct file cases up 18.7% in 2019.
- Recovered money for Medicare, Medicaid and TRICARE.
- Texas OAG MFCU recovered $$140,893,436.69 in 2019.
- Texas HHSC OIG executed 48 settlement agreements for a total recovery of $6,098,716.04.

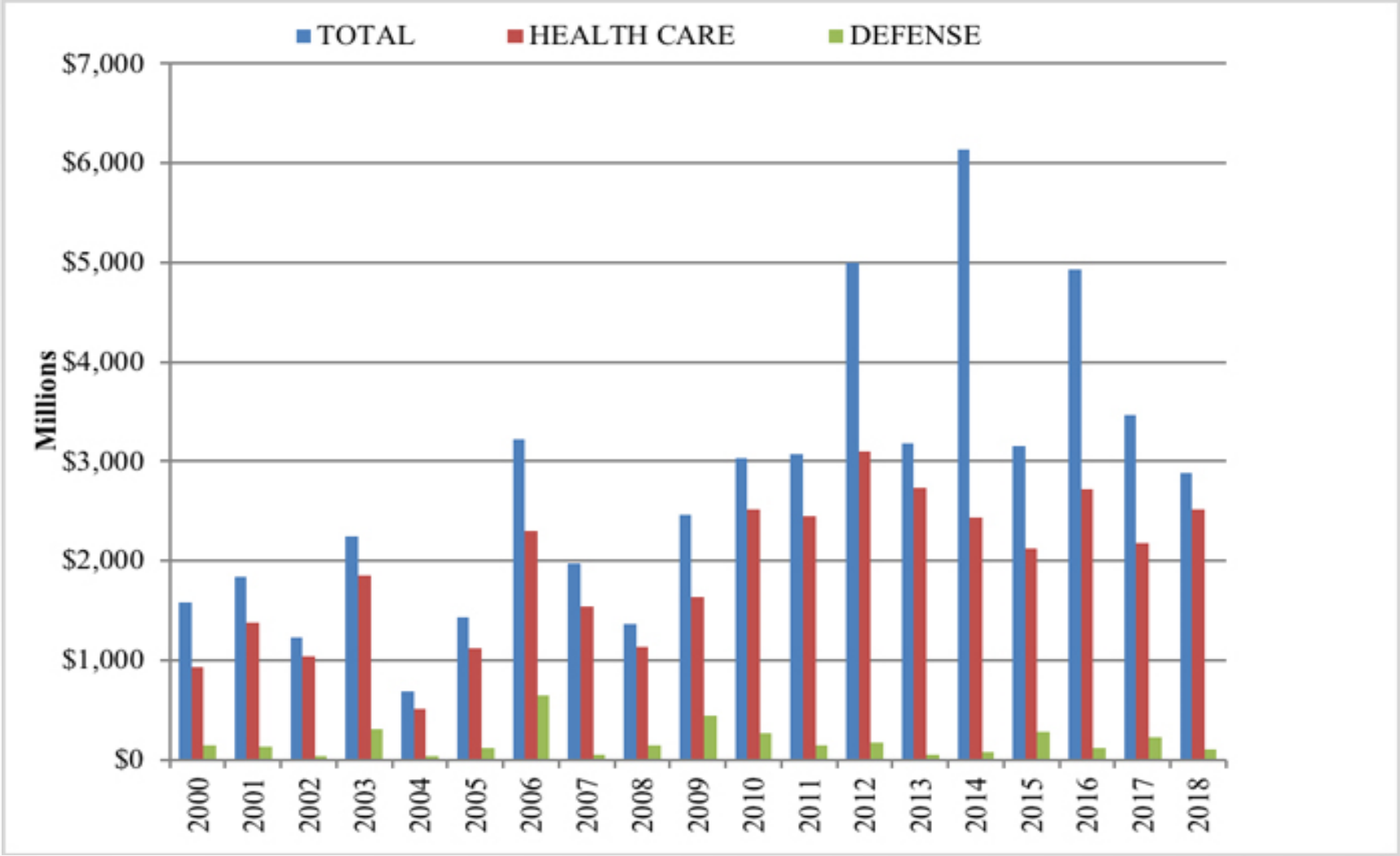
Most Common Conduct

- Services not rendered—documentation and time provided.
- Up-coding—non-existing upgrade procedure or beyond what is necessary
- Unbundling—common in clinical laboratory settings
- False medical necessity certification
- Kickbacks/Improper relationships
- Retention of overpayments

Year to Year Comparisons



Industry Comparison



2019 National Healthcare Fraud Takedown

- Targeted Industries – drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians.
- Two of the largest recoveries in the healthcare industry this past year came from settlements with opioid manufacturers.
- Data analytics continue to identify possible bad actors. Agents are now able to obtain and analyze billing data in real-time.
- 636 new qui tam matters in FY 2019, a drop from 2018 at 646 and 681 in 2017.

Questions?

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