haynesboone

# HEALTH LAW VITALS

A Healthcare Newsletter from Haynes and Boone, LLP

MARCH 2018

## QUICK SHOTS

False Claims Act *Year in Review* highlights key developments in 2017.
**Read more.**

CMS recently unveiled new voluntary bundled payment model called "Bundled Payments for Care Improvement Advanced."
**Read more.**

SAMHSA finalizes changes to clarify health privacy rules for people who seek substance use disorder treatment.
**Read more.**

CMS issued notice of new interest rate for Medicare overpayments and underpayments on January 12, 2018.
**Read more.**

The Texas DHHSC recently posted a Consolidated Credentialing Verification Organization (CVO) Notification Regarding Medicaid and CHIP Updates.
**Read more.**

The FDA's 2018 Compounding Policy Priorities Plan identifies enforcement priorities, promises clarification.
**Read more.**

## FDA Draft Guidance Proposes Risk-Based Regulatory Scheme for Drug Products Labeled as Homeopathics

**Suzie Trigg, Michael Goodman, and Neil Issar**

Suzie Trigg

Michael Goodman

Neil Issar

More than two and a half years after the U.S. Food and Drug Administration (FDA) announced that it was re-evaluating its regulatory framework for homeopathic products, the FDA released its Draft Guidance on **Drug Products Labeled as Homeopathic**. The Draft Guidance summarizes the FDA's current enforcement perspective on homeopathic products and provides a list of the FDA's enforcement priorities.The bills reawakened a debate about the pros and cons of POHs. Critics - mainly the non-profit community and for-profit hospitals - remain concerned that POHs "cherry pick" healthier patients undergoing procedures with higher reimbursement rates. Non-POHs are then left to scavenge on low-reimbursement or non-paying patients, which threatens their existence in an increasingly competitive healthcare environment. Critics also accuse POHs of providing no benefit in terms of cost savings or patient outcomes.

### History of Homeopathic Remedies and Regulation in the United States

Homeopathy has been used around the world since the late 1700s. Generally, it is based on two principles: (1) a substance that *causes* symptoms in a healthy person can be used in a diluted form to *treat* symptoms and illnesses (referred to as "like-cures-like"); and (2) the more diluted a substance, the greater its potency.

The first federal food and drug statute, the Food and Drugs Act of 1906, did not reference homeopathy and instead recognized the U.S. Pharmacopeia (USP) and the National Formulary (NF) as the country's exclusive drug compendia, meaning that only preparations listed in those two publications were defined as "drugs." Preparations that did not conform to the publications' standards could be deemed "adulterated," rendering their manufacture unlawful. At the time, this included preparations listed in the Homeopathic Pharmacopoeia of the United States (HPUS), a recognized compilation of homeopathic medicines published in 1897.

In 1938, the federal Food, Drug, and Cosmetic Act of 1938 (FDCA) included the HPUS as an official compendium alongside the USP and NF and brought homeopathic medicines under the federal law's definition of "drug." Still, homeopathic drugs continued to be informally regulated until the FDA and industry members began working together in the early 1980s to develop a more robust regulatory framework. Six years later, the FDA and the Homeopathic Pharmacists Association issued **Compliance Policy Guide 400.400**, *Conditions Under Which Homeopathic Drugs May be Marketed* ("CPG 400.400"), which outlined how homeopathic medicines should be marketed in the United States.

**Requirements to Market an OTC Homeopathic Drug**

The Draft Guidance does not change preexisting requirements for homeopathic drug labeling or accepted Current Good Manufacturing Practices (CGMPs). A homeopathic drug must be listed in the HPUS and accepted by the Homeopathic Pharmacopoeia Convention of the United States (HPCUS), a nongovernmental organization made up of scientists and clinicians trained in homeopathic medicine that maintains the HPUS. In addition, the Federal Trade Commission holds efficacy and safety claims made in the marketing of over-the-counter homeopathic drugs to the same substantiation standards as similar claims for non-homeopathic drugs.

**The FDA's Enforcement Priorities and New Draft Guidance Document**

The validity of homeopathic principles has been subjected to significant scientific skepticism, but the homeopathic drug market has nonetheless grown into a nearly $3 billion industry. This growth includes an increasing number of untested, unapproved products that may make unsubstantiated health claims, which, in turn, may endanger patients.

The FDA's recently issued Draft Guidance recognizes that the agency lacks the resources to bring enforcement actions against all violators in the expanding homeopathy industry and therefore describes a risk-based approach to enforcement. Specifically, the FDA proposes prioritizing enforcement and regulatory action by evaluating risks associated with products:

- With reported safety concerns
- That contain or purport to contain ingredients associated with potentially significant safety concerns
- Administered other than orally or topically
- Intended to be used for prevention or treatment of serious and/or life-threatening diseases and conditions
- Directed at vulnerable populations
- Deemed adulterated under Section 501 of the FDCA

More simply, the FDA will prioritize targeting products that it believes pose the highest risk. For example, in 2017, the FDA issued warning letters to six manufacturers of homeopathic drug products, including a **warning letter to HomeoCare Laboratories, Inc.** for serious violations related to CGMPs, misbranding, and manufacturing processes that could expose patients to unnecessary risks. In particular, some of HomeoCare's products contained strychnine (rat poison), a highly toxic ingredient associated with potentially significant safety concerns. Further, the company offered drugs for conditions that require diagnosis or treatment by a licensed practitioner but did not comply with corresponding labeling requirements. The warning letter concluded by reiterating the FDA's position regarding homeopathic drugs: They "are subject to the same regulatory requirements as other drugs; nothing in the [FDCA] exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval."

## The Extension of the Texas 1115 Waiver – What is Next?

Michelle "Missy" Apodaca and Kayla Johnson

Michelle "Missy" Apodaca

Kayla Johsnon

With only nine days left before the expiration of the existing 1115 Waiver, in late December 2017, the Centers for Medicare & Medicaid Services (CMS) approved another extension of the 1115(a) demonstration project, "Texas Healthcare Transformation and Quality Improvement Program" (2017 Waiver) for an additional five-year term from October 2017 to September 2022. The 2017 Waiver extension will allow the state to maintain its use of capitated Medicaid managed care model to continue to improve the delivery of healthcare to Texans. The 2017 Waiver is still funded by supplemental payments and managed care savings, but it should be noted that, at an estimated $25 billion over five years, it will receive $2 billion less in funding than the previous 1115 Waiver. According to the Texas Health and Human Services Commission (HHSC) Executive Commissioner, Charles Smith, the renewal "preserves critical support for the state's hospital safety-net" by providing needed funding through the Uncompensated Care (UC) pool, without which, hospitals serving vulnerable patient populations would face potentially insurmountable financial struggles. Whether the renewal ultimately lives up to the Executive Commissioner's lofty expectations remains to be seen; the 2017 Waiver comes with new requirements and potentially far-reaching modifications.

### Prior Texas Waivers

In 2011, Texas's first 1115 Waiver (2011 Waiver) began and was originally set to expire in September 2016, but its term was extended by fifteen months to December 2017. Using the authority and flexibility provided by the 1115 Waiver in designing its Medicaid program, Texas implemented alternative strategies geared primarily toward cost-containment and improvement of statewide access to care.[1] The principal mechanisms through which the 2011 Waiver sought to accomplish its approved objectives included:

- **MMC:** Expansion of Medicaid managed care (MMC) from regional to statewide coverage through STAR, STAR+PLUS, and Children's Medicaid Dental Services
- **UC:** State and federal shift in hospital reimbursement for uncompensated care from the Upper Payment Limit program to an UC pool, which was designed, in part, to change the focus from claims to costs incurred
- **DSRIP:** Creation of an incentive pool, called the "Delivery System Reform Incentive Payment" (DSRIP) program in order to enhance state healthcare infrastructure and develop innovative approaches to improving health care quality and control costs. DSRIP allowed providers to earn payments for meeting certain CMS and HHSC-approved reporting and performance metrics for "a wide range of innovative projects."[2]

The HHSC's May 2017 Final Evaluation Report described the 2011 Waiver as a "massive experiment in transforming health care." The report employed stakeholder surveys to assess overall satisfaction and perceived areas of strength and weakness. Commonly identified strengths included: (i) increased available funding, (ii) opportunities for innovation, (iii) support for partnerships between public and private organizations, and (iv) accountability systems.[3] And, reported areas of weakness related primarily to: (i) the exclusion of certain types of services and providers, (ii) competing priorities and agendas, (iii) limited menu of DSRIP project options, and (iv) time and effort constraints related to defining and understanding new systems for implementing, documenting, and reporting UC and DSRIP activities.[4]

**The 2017 Renewal**

The 2017 Waiver retains the three major components of the 2011 Waiver—statewide Medicaid managed care, the UC pool, and the DSRIP incentive pool—subject, however, to new standards and additional requirements. The most substantial changes among the modifications outlined in CMS's approval relate to the gradual elimination of DSRIP funding and the new method for calculating and distributing UC payments.

DSRIP

Under the 2017 Waiver's terms, federal matching funds of DSRIP activities will be reduced each year until it ceases entirely in 2021, at the end of the fourth year. HHSC must submit a transition plan to CMS, establishing protocols for how delivery system reforms will continue to operate as DSRIP funding is phased out or, alternatively, how DSRIP programs will be phased out along with the funding. In addition, HHSC was required to draft a new Program Funding and Mechanics (PFM) protocol that explains how Texas will implement the new Special Terms and Conditions (STCs) relating to DSRIPs. CMS approved the new PFM and described some of its major updates:

> [Texas] has improved its measure bundles to focus more on outcome measures, added a robust and comprehensive attribution methodology, refined the process by which providers may distribute funding across measure bundles, included a suitable and accountable performance and payment methodology for providers with high or maximized performance baselines, and enhanced how providers will specify, link and report core activities to outcome.[5]

While the DSRIP allowed for innovative healthcare delivery projects and increased access to care under the 2011 Waiver, with the decreased funding and the state's reliance on Medicaid managed care, it is unclear whether there will be any new funding opportunities for health care providers in the 2017 Waiver's DSRIP.

Uncompensated Care

While not as severe on its face, the 2017 Waiver's new methodology regarding the calculation and distribution of UC payments could end up affecting health care delivery in Texas even more than the DSRIP funding wind-up. As a condition of the renewal, the current "UC tool" must be transitioned into a modified "S-10 Worksheet" in order for UC payments to be calculated and distributed based upon hospital charity care costs alone, excluding costs associated with Medicaid shortfall or bad debt. [6] While this will not affect the first two years of the 2017 Waiver, these changes may cause a substantial reduction in UC funding beginning in 2020, which is the first year where UC funding will be directly tied to the new S-10 formulation of charity care costs. [7]

Under the 2011 Waiver, UC pool payments were calculated based on the cost of all services furnished to Medicaid beneficiaries and uninsured patients, minus all payments received. The cost-based payment structure also included the difference between the amount of Medicaid's reimbursement for a given service and what Medicare would pay for that service (i.e., the Medicaid "shortfall" referenced above). The 2011 Waiver's data tool also incorporated a broader definition of charity care than that under the S-10, which defines charity care based on strictly construed principles developed by the Healthcare Financial Management Association.[8] The UC payment protocol (due to CMS by March 30, 2018) must include precise definitions of eligible uncompensated provider charity care costs for each qualifying provider type. After the definitions are established, it will be critical for all providers to accurately report 2017 charity costs, as widespread failure to do so will cause UC payments to default to the reduced amount of $2.3 billion for 2020-2022 until all charity costs have been accurately reported.[9] Moreover, if the HHSC fails to meet any of the prescribed deadlines, CMS will impose a 20% reduction in expenditure authority from the UC pool for the applicable year.

The effective dates of the changes in UC and the winding down of DSRIP funding over the 2017 Waiver's term, as well as other important deadlines to watch, are described in more detail in the table below.

**Conclusion**

As the effects of the 2017 Waiver take shape, the Texas healthcare industry must remain informed about the changes described above and the respective timelines shown below. The funding provided under the 2011 Waiver was instrumental in granting Texas healthcare providers the opportunity to be innovative in their delivery of care, while allowing the state to expand Medicaid managed care. Accordingly, the 2017 Waiver's modifications will likely not change the state's objectives to continue increasing industry integration and access to healthcare via the managed care system. However, as DSRIP will be phased out, it is unclear if some of Waiver's funds will be available to support other programs, or if the original DSRIP projects will be continued or incorporated into managed care. Moreover, the impact of UC pool changes, particularly in relation to charity care hospitals, while currently uncertain, will become more evident with each passing deadline over the new Waiver's five-year term.

| Year | DSRIP Funding | Uncompensated Care Pool | Required Actions and Other Key Dates |
|---|---|---|---|
| 10/1/17 - 9/30/18 | $3.1 Billion | ≈ $3.1 Billion | *1-1-18:* CMS approved HHSC's revised PFM.<br>*3-30-18:* HHSC must submit draft UC funding & reimbursement protocol to CMS.<br>*7-31-18:* Upon CMS approval of UC payment protocol, HHSC must publish notice of proposed rulemaking and public hearing in Texas Register. |
| 10/1/18 - 9/30/19 | $3.1 Billion | ≈ $3.1 Billion | *1-30-19:* HHSC must publish final administrative rules to implement required UC pool distribution methodology, to be effective by *9-30-19*.<br>*5-1-19:* HHSC must submit revised UC application tools for all provider types.<br>*8-31-19:* CMS deadline for approving revised UC tools.<br>*9-30-19:* Final effective date for Texas Administrative Code rules on UC pool distribution methodology. |
| 10/1/19 - 9/30/20 | Reduced to $2.9 Billion | Resized & adjusted based on 2017 S-10 charity care costs (or $2.3 billion default) | *10-1-19:* New UC pool distribution methodology implemented.<br>*10-1-19:* HHSC must submit DSRIP transition plan to CMS.<br>*3-31-20:* Final DSRIP transition plan must be approved by CMS. |
| 10/1/20- 9/30/21 | Reduced to $2.5 Billion | Resized & adjusted based on 2017 S-10 charity care costs (or $2.3 billion default) | |
| 10/1/21- 9/30/22 | No Funding | Resized & adjusted based on 2017 S-10 charity care costs (or $2.3 billion default) | *10-1-21:* Federal matching funds for DSRIP are discontinued. |

[1] Letter from John Cornyn, Senator, et al., U.S. CONGRESS to Hon. Thomas E. Price, M.D., Sec., DHHS, & Hon. Seema Verma, Admin., CMS (June 7, 2017).
[2] *Evaluation of the 1115(a) Tex. Demonstration Waiver – Healthcare Transformation and Quality Improvement*, Final Evaluation Report, TEX. HHSC (May 30, 2017).
[3] *Id.* at 30.
[4] *Id.* at 29.
[5] Letter of approval from CMS Dir. of Sys. Reform and Demonstrations to Stephanie Muth, Texas Medicaid Assoc. Comm'r. of Medicaid and CHIP (Jan. 19, 2018).
[6] Certain hospitals—primarily children's, cancer, and rehabilitation hospitals—will not be required to complete the S-10, in which case an alternate methodology using CMS-approved cost reports will be used to determine charity costs. See Letter of approval from Seema Verma, Admin., CMS, to Charles Smith, Exec. Comm'r, HSSC; *see also* Milestones for Texas' New Medicaid 1115 Waiver, TEX. HOSP. ASS'N (Jan. 2018) (hereinafter *Milestones*).
[7] *See Milestones, supra*, note 14.
[8] HMA Weekly Roundup: Trends in State Health Policy, HEALTH MGMT. ASSOCS. (Jan. 24, 2018).
[9] *Texas Medicaid Waiver Renewal – Summary,* HHSC RATE ANALYSIS DEPT (Dec. 29, 2017).

## The New Framework for Characterizing the Deductibility of FCA Settlement Payments

Stacy Brainin and Taryn McDonald

Stacy Brainin

Taryn McDonald

In addition to its certain impact within the general realm of finance and business, the December 2017 passage of the Tax Cuts and Jobs Act may have somewhat less obvious, but equally important, implications for the delivery of healthcare and the industry as a whole. Some of the new law's key healthcare policy changes relate to the individual mandate, medical expense deductions, and the Orphan Drug Tax Credit; however, the particular implications of these changes are largely speculative at this time. On the other hand, the change to the deductibility of settlements with government agencies under Internal Revenue Code (Code) § 162(f), though not specifically aimed at healthcare, may nonetheless have the most immediate impact on industry operations.

### Section 162 and its Storied History with FCA Settlements

In general, Section 162 of the Code allows for deductions of "all the ordinary and necessary expenses paid or incurred during the taxable year in carrying on any trade of business."[1] Payments made in settling claims brought against any business may constitute such ordinary and necessary expenses under Section 162. For taxpayers settling False Claims Act (FCA) actions, the tax treatment of amounts paid to settle is significant, but the application of Section 162 has not always been clear in this context.

Historically, the Code prohibited deducting as a business expense any fines, penalties, or other amounts paid to the government or to a governmental entity for the violation of any law or the investigation by the government into the potential violation of any law.[2] The Treasury regulations defined a "fine or similar penalty" to include amounts "[p]aid as a civil penalty imposed by Federal, State, or local law" and amounts "paid in settlement of the taxpayer's actual or potential liability for a fine or penalty (civil or criminal)."[3] However, "[c]ompensatory damages . . . paid to a government do not constitute a fine or penalty."[4] In an effort to clarify how these rules apply to FCA settlements, the IRS issued a memorandum in 1972, explaining that single damages paid under the FCA would be deductible, but any additional amounts paid as penalties would not be deductible.[5] Distinguishing compensation from penalties has proven difficult for FCA defendants, as the FCA's treble damages provision serves both remedial and punitive purposes, depending on the parties' intent.[6]

Courts have also weighed in on the subject. In 2001, the Ninth Circuit affirmed a tax court's decision that the absence of a tax characterization agreement, when a settlement agreement was silent on the issue and the parties disagreed, was fatal to the taxpayer's

desired deduction.[7] The tax court instructed that it was the taxpayer who suffered the consequences if he did not establish "entitlement to the disputed deduction."[8] However, in 2014, the First Circuit expressly rejected any "rule that requires tax characterization as a precondition to deductibility," as such would give the government unprecedented power in that it "could always defeat deductibility by the simple expedient of refusing to agree—no matter how arbitrarily—to the tax characterization of a payment."[9] The burden remained on the taxpayer to prove deductibility, but the Department of Justice (DOJ) has historically refused to take a position on which portion of an FCA settlement payment is compensatory and which is punitive. Accordingly, settling FCA defendants have faced uncertainty as to which portion of a settlement payment is compensatory and therefore deductible, especially in cases settled for a much smaller figure than the Department of Justice initially requested.

**The New Tax Law**

The new tax law looks to put an end to some of this uncertainty by amending Section 162(f), but not without consequence to FCA defendants. As amended, Section 162(f) states that, absent certain exceptions:

> [N]o deduction otherwise allowable shall be allowed under this chapter for any amount paid or incurred (whether by suit, agreement, or otherwise) to, or at the direction of, a government or governmental entity in relation to the violation of any law or the investigation or inquiry by such government or entity into the potential violation of any law.[10]

The first exception excludes any amounts paid as restitution if (i) the taxpayer establishes that the amounts constitute restitution or that the amounts are paid to come into compliance with the law that was violated or otherwise involved in the investigation or inquiry, and (ii) the amounts are identified as restitution or amounts paid to come into compliance with such law *in the court order or settlement agreement*. Importantly, the law indicates that "[t]he identification alone [in the settlement agreement or court order] is not sufficient to establish the amounts as restitution."[11]

Under the new tax law, settling FCA defendants must (i) establish that the amounts they wish to deduct constitute restitution or were paid to come into compliance with any law which was violated or otherwise involved in the investigation, and (ii) ensure that those amounts are identified as such in the relevant court order or settlement agreement. The law also includes a requirement that the appropriate official of any government or entity involved in such a settlement make a return that sets forth: (i) the total amount to be paid, (ii) the portion of the amount that constitutes restitution or remediation of property, and (iii) the portion of that amount required to be paid to come into compliance with any law that was violated or involved in the investigation.[12] The return must be filed at the time the agreement is entered into. The law further requires that the government or entity making the return provide a written statement to each person who is a party to the suit or agreement containing the information supplied in the return.

**Conclusion**

For FCA defendants, the primary effect of the new tax law's amendment to Section 162(f) is that characterization of amounts paid will be a key term in the negotiation of any settlement. Settling defendants should be able to demonstrate which amounts constitute "restitution or an amount paid to come into compliance," and those amounts should be agreed to by both parties and identified as such in the settlement agreement. In any event, the new tax

law will, at least, alter the nature of FCA negotiations, as the DOJ may now have to take a position as to the characterization of amounts paid for tax purposes.

[1] 26 U.S.C. § 162(a).
[2] 26 U.S.C. § 162(f).
[3] *26 C.F.R. § 1.162-21(b)(1).*
[4] 26 C.F.R. § 1.162-21(b)(2).
[5] 1972 TM LEXIS 15, at *8 (July 25, 1972).
[6] *See Cook Cnty. V. U.S. ex rel. Chandler*, 538 U.S. 119, 130-31 (2003).
[7] *See Talley Indus., Inc. v. Comm'r*, No. 27826-92, 1999 T.C. Memo, LEXIS 237, at *23 (June 18, 1999), aff'd 18 F. App'x 661 (9th Cir. 2001).
[8] *Id.*
[9] *Fresenius Med. Care Holdings, Inc. v. United States*, 763 F.3d 64, 70 (1st Cir. 2014).
[10] H.R. REP. NO. 115-466 § 13306(a) (2017) (Conf. Rep.).
[11] *Id.*
[12] *See id.* § 6050X(a).

## How Should Restaurants Handle and Declare Major Food Allergens?

**Suzie Trigg and Kayla Johnson**

Suzie Trigg

Kayla Johnson

Although many restaurants are not in states that require food allergens to be declared on menus, the declaration (or labeling) and handling of food allergens is a growing concern for restaurants, due to the significant risks of liability and poor public relations, if handled incorrectly. Restaurants should create careful plans to address food allergens, from ensuring that food product suppliers provide comprehensive allergen checklists to training food handlers in methods to prevent cross-contact among food products that contain major food allergens and those that do not.

According to the Centers for Disease Control and Prevention (CDC), food allergies affect an estimated 15 million people in the United States and are reportedly responsible for 30,000 emergency room visits and between 150 and 200 deaths each year.[1] As there is no cure for food allergies, the only way to prevent potentially harmful, sometimes life-threatening, reactions is to avoid the applicable allergens entirely. This has proven to be particularly difficult in the restaurant setting where the safety of food-sensitive consumers is threatened by issues like miscommunication between and among restaurant staff and customers, unexpected or hidden food allergens, and cross-contact during food preparation. Accordingly, regulatory oversight of restaurants has increased, and additional laws have emerged as tools to hold food establishments legally responsible for how they are handling allergens. To ensure customer safety and legal compliance, restaurants must be aware of the applicable laws and implement proper protocols for the treatment of food allergens.

### Federal Allergen Laws

There are currently two federal statutes that relate to food allergens: the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and the FDA Food Safety Modernization Act of 2011 (FSMA). FALCPA mandates the labeling of certain packaged food products and thus does not apply to restaurants, but it may be instructive as to the most important legislative safety concerns and applicable best practices.[2] Importantly, FALCPA identifies the eight allergens that are responsible for 90% of reactions to food allergens in the U.S.: milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans. To the extent that a packaged food product contains any of these allergens, it must comply with FALCPA.

FSMA and the applicable implementing regulations set forth at 21 CFR Part 117, in relevant part, requires that the operator of a food facility have a written plan, which: (i) identifies and evaluates known and reasonably foreseeable hazards; (ii) identifies and implements preventative controls to minimize the risks; (iii) monitors the effectiveness of such controls;

(iv) establishes corrective actions upon failure of preventative controls; (v) verifies plan function; and (vi) maintains records to demonstrate the plan's effectiveness.[3] Allergens are included in the list of foreseeable hazards under FSMA, which means that restaurant operators must have written risk-based preventative control plans for handling allergens that comply with the above requirements.

**State Food Allergy Awareness Legislation**

Many state legislatures have followed the federal government's lead having enacted consumer protection statutes with food allergen provisions. Because of the dangers associated with food-sensitive consumers' inadvertent consumption of products that contain or have come in contact with a major food allergen, a number of state departments of health have promulgated rules requiring restaurant employees to be "properly trained in food safety, including food allergy awareness, as it relates to their assigned duties."[4] In addition, recently enacted statutes in Maryland, Massachusetts, Rhode Island, Virginia, Illinois, and Michigan have set forth standards specifically designed to promote food allergy awareness in restaurants. Similar legislation has been proposed in Arizona, Connecticut, and New Jersey.[5] In general, these statutes require food service establishments to:

- Display an educational poster in the employee work area covering allergens and related issues
- Display on menus, menu boards, or at the point of service, a statement similar to the following: "Before placing your order, please inform your server if a person in your party has a food allergy"
- Have at least one certified food protection manager who has received food allergen awareness training

The Illinois statute additionally requires that all restaurant food handlers receive American National Standards Institute-accredited training in basic safe food handling principles within thirty days of employment and every three years thereafter.[6] This requirement is designed to combat issues with allergen cross-contact. More states are expected to join the ranks of those described above in developing and implementing food allergy awareness legislation, but it is important to note that the absence of a state food allergy awareness statute does not equate to the absence of liability for restaurants that mishandle allergens.

**The Americans with Disabilities Act as an Additional Source of Liability**

Regardless of whether a given state has enacted legislation, restaurants must take the necessary steps to comply with best practices for handling food allergens, as there are numerous other potential sources of liability, including common law tort doctrines (primarily failure to warn) and, more recently, the Americans with Disabilities Act (ADA). While common law theories of liability have been largely unsuccessful due to the difficulty of proving causation in this context, recent amendments have broadened the scope of the ADA, such that a severe food allergy may be recognized as a legally cognizable disability.[7] The Department of Justice (DOJ) confirmed the ADA's expansion to food allergens in 2012, as it brought an action against Lesley University in Cambridge, Massachusetts, for its failure to offer gluten-free options within its mandatory meal plan. The DOJ ultimately entered into a settlement agreement with the University, which purported "to ensure that students with celiac disease and other food allergies would be able to fully and equally enjoy the university's food services in compliance with the Americans with Disabilities Act (ADA)."[8]

The DOJ distinguished restaurants from universities like Lesley, as restaurants do not have mandatory meal plans and, accordingly, are not be *required* to serve gluten-free or allergen-free options. Instead, according to the DOJ, restaurants may have to take "some reasonable steps to accommodate individuals with

disabilities where it does not result in a fundamental alteration of that restaurant's operations."[9] This may include (i) "answering questions from diners about menu item ingredients, where the ingredients are known," or (ii) "omitting or substituting certain ingredients upon request if the restaurant normally does this for other customers."[10]

**Recommended Practices**

Each of the laws addressed herein can be instructive for restaurants in developing and implementing internal policies for handling food allergens in a safe, compliant manner. However, efforts must go beyond compliance with an allergy awareness statute. While certainly a step in the right direction, the effectiveness of internal awareness-centric protocols is limited to managing risks associated with *intentional* allergen presence. A truly comprehensive system for handling and declaring allergens must also account for the *unintentional* presence of allergens, which can only be done by addressing and safeguarding against potential hazards at each key phase of food production, starting with the raw ingredients and ending with the final product placed in front of guests. While there is no one-size-fits-all formula, the following general considerations are critical in developing and implementing an effective plan:[11]

*Supply Chain Management/Sourcing:* The in-house operations of a restaurant will only be successful in handling food allergens if there are systems in place to ensure adequate control over what comes into the facility from suppliers. ACPs should establish policies for reviewing and documenting how allergens are treated at every step along the food supply chain. Restaurant operators must solicit information about the ingredients used by suppliers, as well as documentation describing suppliers' production practices as they relate to preventing cross-utilization of equipment or other cross-contamination. For example, many restaurants obtain an allergen checklist from each supplier, which requires the supplier to list possible allergens and respond to specific questions about how allergens are handled during food production.

*The Menu:* Maintaining updated, allergen-friendly menus is a challenge for many restaurants, as menus are subject to frequent changes. However, to the extent possible, menus should inform consumers when food allergens are ingredients in menu items. The following chart provides examples of simple menu changes that may better alert consumers as to the presence of food allergens: [12]

| Instead of: | Describe as: |
|---|---|
| Apple Cake | Apple-Walnut Cake |
| Blue Cheese Dressing | Blue Cheese and Walnut Dressing |
| Chicken Stir-Fry | Chicken Cashew Stir-Fry |
| Asian Noodles | Asian Noodles with Peanuts |
| Pasta with Pesto | Pasta with Pesto (Contains Pine Nuts) |

Additionally, many food-sensitive patrons explore a restaurant's website/online menu before a dining experience in search of any information about food allergens. Thus, the website may be an effective first step in opening the lines of communication between patrons and restaurant staff. At the very least, menus should include a phrase similar to those required under the allergy-awareness statutes described above (e.g., "Before placing your order, please inform your server if a person in your party has a food allergy.").

*Internal Operations:* After tackling supply chain management and menu issues, restaurants should confront its internal operations and develop clear, consistent protocols for both front-of-house and back-of-house allergen treatment. Typically, the primary elements of a restaurant's internal allergen control plan relate to (i) staff training, (ii) preventing cross-contact, and (iii) communication with guests. The National Restaurant Association (NRA) suggests the following action steps for restaurants generally seeking to establish or improve allergen treatment practices:

1. **Train staff on proper handling of food allergens**—ServSafe has partnered with Food Allergy Research & Education (FARE) in creating a comprehensive online course designed to provide restaurant employees and managers with critical information needed to accommodate guests with food allergies and respond to emergencies. [13]
2. **Involve a certified manager to establish and maintain open dialogue with customers**.
3. **Create a back-of-house system for allergen-specific equipment**—Consider using color-coded, allergen-specific plateware, prepware, and other equipment.
4. **Make ingredient lists available to guests**.
5. **Sub-out widely used allergens**.
6. **Never Guess**—Ensure that employees understand that they should never guess when asked a food allergy question they cannot answer and should instead consult a manager.
7. **Invest in allergy-specific technology**—Some restaurants have implemented technology that involves an "allergy key," which front-of-house employees press to alert the back-of-house and a manager whenever a customer has a food allergy.

**Conclusion**

As the prevalence of food allergies continues to grow, restaurants will be held to a perpetually increasing standard of care for handling and declaring food allergens. Restaurant operators should seriously consider the advantages of utilizing an online training course as a means to stay up to date with best practices and eliminate the guess work in allergen control and prevention. Regardless of the chosen methods, restaurants must take an integrative approach to developing and implementing allergen policies that confronts and mitigates risks at all stages in the food supply chain.

---

[1] Laura G. Brown, et al., *Restaurant Food Allergy Practices – Six Selected Sites, United States 2014*, CENTERS FOR DISEASE CONTROL & PREVENTION MORBIDITY & MORTALITY WEEKLY REPORT.
[2] 21 U.S.C.A. § 301 Note (2004).
[3] 21 U.S.C. § 350g.
[4] *See,* e.g., MODEL FOOD CODE § 2-103.11(M) (2013).
[5] *See,* e.g., 105 C.M.R. 590.009(H)(1).
[6] IL. Gen. Assembly. Pub. L. No. 100-0367.
[7] 42 U.S.C.A. § 12102 (West).
[8] Press Release, U.S. Department of Justice, *Justice Department and Lesley University Sign Agreement to Ensure Meal Plan is Inclusive of Students with Celiac Disease and Food Allergies* (Dec. 20, 2012).
[9] *Questions and Answers About the Lesley University Agreement and Potential Implications for Individuals with Food Allergies*, U.S. DEPARTMENT OF JUSTICE, CIVIL RIGHTS DIVISION, DISABILITY RIGHTS SECTION (Jan. 23, 2013).
[10] *Id.*
[11] The considerations described in this section synthesize recommendations from various industry experts, including the National Restaurant Association, Food Safety Magazine, and the USDA Food Safety and Inspection Service (FSIS). *See Allergy-Friendly Practices to Protect Guests and Increase Your Business*, NATIONAL RESTAURANT ASSOCIATION (Last visited Feb. 13, 2018); *Putting Together an Effective Allergen Control Plan*, FOOD SAFETY MAGAZINE (Oct./Nov. 2017); *Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling*, FSIS COMPLIANCE GUIDELINES (Nov. 2015).
[12] *Welcoming Guests with Food Allergies,* THE FOOD ALLERGY AND ANAPHYLAXIS NETWORK (FAAN) (2010).
[13] ServSafe Allergens Training.

## UPCOMING SPEAKING ENGAGEMENTS

**Tax Reform: Changes to Employee Benefits and Executive Compensation**

**2018 Fort Worth Chamber of Commerce Employment Law Update**

**Scott Thompson**

March 29, 2018
Fort Worth, Texas

**2018 State and Federal Healthcare Legislative Landscape**

**UT Law 30th Annual Health Law Conference**

**Michelle "Missy" D. Apodaca**

April 5, 2018
Houston, Texas

**Survival Strategies for Physician-Owned Entities**

**UT Law 30th Annual Health Law Conference**

**Kenya Woodruff**

April 5, 2018
Houston, Texas

**Innovative Wellness and Franchising – A Franchisor's Guide to FDA, FTC, and State Regulatory**

**Dallas Bar Association Meeting**

**Suzie Trigg and Priscilla Bowens**

April 17, 2018
Dallas, Texas

We'd like to hear your feedback and suggestions for future newsletters. Please contact:

**KENYA WOODRUFF**
PARTNER | CHAIR -
HEALTHCARE PRACTICE GROUP
kenya.woodruff@haynesboone.com