

**Conference for Food Protection
2018 Issue Form**

Issue: 2018 I-015

Council Recommendation: Accepted as Submitted _____ Accepted as Amended _____ No Action _____

Delegate Action: Accepted _____ Rejected _____

All information above the line is for conference use only.

Issue History:

This is a brand new Issue.

Title:

Amend Food Code Consumer Advisory: Food Allergies - Allergen Disclosure

Issue you would like the Conference to consider:

The FDA Food Code recognizes that consumers should have notice regarding the risk of foodborne illness from raw or undercooked meats, poultry, seafood, shellfish, or eggs. However, the model consumer advisory fails to provide adequate notice for persons to accurately assess the risk of severe illness and death from the known regulated US Food & Drug Administration (FDA) eight (8) food allergens. Specifically, the eight foods identified by the FDA law are: Milk, Eggs, Fish, (e.g., bass, flounder, cod) Crustacean shellfish, (e.g., crab, lobster, shrimp) Tree nuts, (e.g., almonds, walnuts, pecans) Peanuts, Wheat, Soybeans.

Every country is impacted by food allergies as it is a significant public health concern and global burden that impacts every social culture. Other developed countries such as the United Kingdom and the European Nations (EU) require Food Service Operations (FSO) to list/disclose regulated food allergens on the menu per customer request. The EU requires that each FBO needs to define this to know the ingredients in the menu items they are serving/selling. 7 Food safety laws do not allow servers and/or chefs to say they do not know what regulated allergens are on their menu nor are they allowed to say that all the items contain an allergen. Simply put, ignorance is no excuse for lack of food allergen safety. Like any other manufacturing/product industry, restaurants and take-outs must know and disclose what regulated food allergens are contained in products listed on the menu when asked by the consumer.

Currently, retail food service establishments in the United States are not required to know the food allergens contained in foods listed on the menu. Given the potential for food allergy exposures that can result in hospitalizations, lost work, accidental illness and death, retail food service should be required to know what regulated food allergens (FDA's eight (8) food allergens) are contained in food menu products.

The EU requires every Food Business Operation (FBO) to disclose each known regulated food allergen ingredient upon request (Note: EU has 14 food allergens, compared to the 8

food allergens in the US- From 13 December 2014, the EU Food Information for Consumers Regulation No. 1169/2011 requires food businesses to provide allergy information on food sold unpackaged, in for example catering outlets, deli counters, bakeries and sandwich bars). It is time for the United States to join other developed countries and take steps to reduce exposure to food allergens. Therefore, I am proposing that retail food service establishments provide a Material Safety Data Sheet "MSDS" for staff and customers to be available upon request. I have attached an example which is used in the EU and is incorporated into a food service operator's restaurant plan review process. Typically, it is part of the already created recipe and food menu creation process by chefs, that is shared with servers.

Public Health Significance:

Direct quote from the FDA Website:

<https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAllergens/default.htm>

"Each year, millions of Americans have allergic reactions to food. Although most food allergies cause relatively mild symptoms some food allergies can cause severe reactions that are life-threatening.

There is no cure for food allergies. Strict avoidance of food allergens and early recognition and management of allergic reactions to food are important measures to prevent serious health consequences".

Food allergies are a significant and emerging public health concern and impact approximately 15 million Americans, including 5.9 million children under the age of 18. That's 1 in 13 children or roughly two in every classroom. Economically, the eight (8) food allergens cost US families 25 billion dollars annually. In addition, tax funded local, state and federal food safety agencies are forced to respond to what can be a preventable food safety/poisoning-type exposure. It also should be noted that a food allergy is an impairment that limits a major life activity and may qualify an individual for protection under the Americans with Disabilities Act of 1990 (ADA) and Section 504 of the Rehabilitation Act of 1973. 2

The Centers for Disease Control & Prevention reports that the prevalence of food allergies in children increased by 50 percent between 1997 and 2011. Given there is no cure for food allergies, public health prevention measures remain the best method to reduce the number of anaphylactic reactions that result in the following:

- Every three minutes, a food allergy reaction sends someone to the emergency room. 1
- Each year in the U.S., 200,000 people require emergency medical care for allergic reactions to food. 2
- Pediatric hospitalizations for food allergies tripled between the late 1990s and the mid - 2000s. Between 2004 and 2006, an average of 9,500 children received in - patient hospital care for food allergies each year. 3
- About 40 percent of children with food allergies have experienced a severe allergic reaction such as anaphylaxis. 4
- Each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food. 6

The Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) (FALCPA) improved food labeling information for the millions of consumers who suffer from food allergies. The Act is especially helpful to children who must learn to recognize the allergens they must avoid.

Furthermore, according to the Food Allergen Labeling and Consumer Protection Act (FALCPA) the eight major allergens must be declared in simple terms either in the ingredient list or via a separate allergen statement. However, FALCPA does not regulate the use of advisory/precautionary labeling (e.g., "may contain," "made in a facility that also processes"). 5

Like other developed countries similar to the United States, affording consumers information to make informed decisions provides them the opportunity to prevent unintended food allergen exposures. Given there is no cure, prevention is the best public health food safety control method to prevent unintended illness and death.

References: (Note : For all sections of this form)

1. Clark S, Espinola J, Rudders SA, Banerji, A, Camargo CA. Frequency of US emergency department visits for food - related acute allergic reactions. J Allergy Clin Immunol. 2011; 127(3):682 - 683.

2. U.S. Department of Education, Office for Civil Rights. Questions and Answers on the ADA Amendments Act of 2008 for Students with Disabilities Attending Public Elementary and Secondary Schools. <http://www2.ed.gov/about/offices/list/ocr/docs/dcl - 504faq - 201109.html>, retrieved December 28, 2015.

3. Branum A, Lukacs S. Food allergy among U.S. children: Trends in prevalence and hospitalizations. NCHS data brief, no 10. Hyattsville, MD: National Center for Health Statistics. 2008. Retrieved from www.cdc.gov/nchs/data/databriefs/db10.htm

4. Gupta RS, Springston MR, Warrier BS, Rajesh K, Pongracic J, Holl JL. The prevalence, severity, and distribution of childhood food allergy in the United States. Pediatrics 2011; 128(1):e9 - 17.

5. NIAID - Sponsored Expert Panel. Guidelines for the diagnosis and management of food allergy in the United States: Report of the NIAID - sponsored expert panel. J Allergy Clin Immunol. 2010; 126(6):S1 - 58

6. <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm106187.htm>

7. Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance. April 2015

Content Documents: Attached please a food allergy chart that has been used in the EU for many years as an example for consumer disclosure and to assist FBO's. In addition, please find the

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance. April 2015

Recommended Solution: The Conference recommends...:

That a letter be sent to the FDA requesting § 3-603.11, Consumption of Animal Foods that are Raw, Undercooked, or Not Otherwise Processed to Eliminate Pathogens, of the most current edition of the FDA Food Code be amended as follows (new language underlined):

(D) FOOD ALLERGEN DISCLOSURE shall include a statement on the menu indicating that upon request by a consumer, the PERSON IN CHARGE shall provide (1) additional information about the menu showing where the eight MAJOR FOOD ALLERGENS are used as ingredients and (2) The following REMINDER statement: Consuming food allergens may cause a severe allergic reaction to a person who diagnosed with a FOOD allergy.

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Supporting Attachments:

- "1. EU Food Allergy Regulation N0. 1169/2011 (2015)"
- "FSA Food Allergen Information & Disclosure Chart / MSDS Form"
- "Food Allergy White Paper"

It is the policy of the Conference for Food Protection to not accept Issues that would endorse a brand name or a commercial proprietary process.

Food allergen labelling and information requirements under the EU Food Information for Consumers Regulation No. 1169/2011: Technical Guidance

April 2015

For all queries about this guidance — including if you require the information in an alternative format such as audio, large print or Braille — please get in touch using the information below.

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Summary

Intended audience:	<ul style="list-style-type: none"> • All food manufacturers and producers • Retailers, institutional caterers and other food businesses • Enforcement authorities • Packers • Importers
Which UK nations does this cover?	England, Wales, Scotland and Northern Ireland
Purpose:	To support food businesses (including institutional caterers, such as workplace canteens, schools and hospitals, and carers), especially small and medium sized enterprises, in following allergen requirements on labelling and providing information. To also assist authorised food officers at local food authorities in enforcing these measures. Technical advice on the interpretation and application of the requirements is provided.
Legal status:	This guidance is intended to accompany the allergen provisions of the EU Food Information for Consumers Regulation (No. 1169/2011) and Food Information Regulations 2014 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.
Key words	<ul style="list-style-type: none"> • Food allergy and intolerance • Allergen labelling • Prepacked foods • Non-prepacked foods • Distance selling
Review date	1 July 2016
Sunset date	Not applicable

Revision history

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please let us know by emailing betterregulation@foodstandards.gsi.gov.uk. If you have any comments on the guidance itself, please call us using the contact number on page 2 or complete our ongoing [Guidance survey](#): <https://www.surveymonkey.com/s/55QQDCG>

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
1	10 April 2015	Updated advice in paras 1, 10, 14 – 20, 31, 33, 34, 36, 39, 40, 48 – 50, 52, 55, 56, 58, 59, 65, 66 (example), 72, 73, 74 – 76, 78, 79, 82, 83, 90 – 93, 95 – 98 and References and Resources page	Food Allergy Branch

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Introduction

1. These guidance notes cover the interpretation and application of allergen provisions for prepacked, prepacked for direct sale and non-prepacked foods, which can be found in the EU Food Information for Consumers Regulation (No. 1169/2011) (EU FIC) <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF> and Commission Delegated Regulation (EU) No. 78/2014 amending Annex II of 1169/2011. The allergen rules came into effect in the UK and the EU on 13 December 2014. The allergen labelling rules for prepacked products apply to products placed on the market or labelled on or after this date. For non-prepacked foods, the allergen information rules apply to foods placed on the market on or after 13 December 2014. Failure to comply with the allergen provisions may result in criminal prosecution being brought against a food business operator (FBO) (see p 34 for details on enforcement of measures).
2. This guidance does not cover other labelling requirements (such as other general labelling (e.g. country of origin, minced meat, quantities, additives, nutrition etc.).
3. The EU FIC does not affect the legal basis for the application of voluntary precautionary allergen statements to indicate the unintentional presence of allergens due to cross contamination such as “*may contain x, y, z*”. Precautionary allergen statements should only be used after a thorough risk assessment and where there is considered to be a real risk to the consumer.

Intended audience

4. These guidance notes on EU FIC’s rules on allergen labelling and information are intended to help food businesses such as producers, manufacturers, packers, importers, distributors, wholesalers, retailers, caterers and also for enforcement officers responsible for enforcing relevant measures.
5. Individuals who are not food businesses and occasionally provide food at charity events or voluntary cake sales, for example, do not need to follow these requirements.

Purpose of guidance

6. These guidance notes have been produced to:
 - provide informal and non-binding technical guidance on the interpretation and practical application of EU FIC's specific requirements on allergen labelling and information.
 - develop understanding by providing regulatory guidance and interpretation in this area.
 - be read alongside the EU Food Information for Consumers Regulation (No. 1169/2011) (EU FIC) and Food Information Regulation (FIR) 2014 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.

Legal status of guidance

7. These notes have been produced to provide practical guidance about allergen labelling of prepacked food and allergen information provision for non-prepacked foods.
8. These notes have been produced to provide guidance on:
 - the legal requirements of the EU Food Information for Consumers Regulation (No. 1169/2011)
 - enforcement and penalties outlined in the Food Information Regulations 2014 (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland.
 - examples of how to comply with the legal provisions.

These guidance notes on legal requirements cannot cover every situation and you may need to consider the relevant legislation itself and other parallel legislation to see how it applies in your circumstances. If you do follow the guidance notes they will help you to comply with the law.

Examples of ways in which businesses can provide allergen information to comply with the legal provisions are also given. **To separate the legal provisions from**

examples of what compliance could look like, they are provided in shaded boxes with the heading of 'Examples'. You are not required by law to use these particular examples as other approaches may also be compliant.

9. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/ environmental health department of the Local Authority.

General background on allergens

10. EU FIC changes how allergen information is provided and presented for all foods.
11. In the UK, it is estimated that 1-2% of adults and 5-8% of children have a food allergy. This equates to around 2 million people living in the UK with a food allergy, this figure does not include those with food intolerances. This means the actual number of affected people living with food allergy and/or food intolerance is considerably more.
12. An allergic reaction can be produced by a tiny amount of a food ingredient that a person is sensitive to (for example a teaspoon of milk powder, a fragment of peanut or just one or two sesame seeds). Symptoms of an allergic reaction can range from mild symptoms such as itching around the mouth and rashes; and can progress to more severe symptoms such as vomiting, diarrhoea, wheezing and on occasion anaphylaxis (shock). Around ten people in the UK die from allergic reactions to food every year.
13. There is no cure for food allergy. The only way to manage the condition is to avoid food that makes the person ill. This can be achieved by checking ingredients details on labels of prepacked foods and being provided allergen ingredients information for non-prepacked foods. Therefore, it is very important that food businesses provide clear and accurate information about allergenic ingredients in their products. EU FIC introduces new rules for food businesses relating to the labelling and provision of allergen information.

Main allergen labelling changes

14. Food businesses who supply prepacked foods already follow specific requirements. The EU FIC however, introduced a new requirement to emphasise any of the 14 specific allergens in the ingredients list of prepacked food.
15. Prepacked products with old style allergen labelling that were placed on the market or labelled before 13 December 2014 can be sold through until stocks have been exhausted. Products such as frozen, tinned or dried food have a long shelf life. It will be possible therefore to see both types of labelling being used on these types of products for a few years after the application date.
16. For food businesses which provide non-prepacked food, such as retailers, restaurants, takeaways, bakeries and institutional caterers (prisons, nurseries, schools, hospitals, workplace canteens etc.), the EU FIC introduced a new requirement to provide information on allergenic ingredients. This information can be provided in writing and/or orally.
17. In specific circumstances where individuals are owed a duty of care by those providing them with food, such as in prisons, nurseries, schools and hospitals; a process should be put in place to safeguard those individuals, especially those unable to communicate their dietary needs (for example the very young or those with mental illness). The process needs to ensure that allergen information is recorded and reported in line with EU FIC and requirements in other legislation concerning the adult mental capacity and care for minors, such as the Mental Capacity Act 2005 and the Children Act 1989 respectively, should also be considered. For example, where the individual cannot make a safe dietary choice, the caregiver should be able to identify that individual and provide them with food which is safe for their consumption.
18. EU FIC and the FIR allergen requirements makes clear when the food business has not complied with the allergen provisions (i.e. for non-prepacked food it is clear how the FBO should provide allergen information and, for prepacked foods, how information should be declared on the label). Failure to meet the allergen requirements is a criminal offence due to the impact of non-compliance on public health. Details on local authority responsibilities and penalties are covered on p34 of this guidance.

Mandatory obligations for all FBOs

19. Under Article 9 (1)(c) of EU FIC, all FBOs should declare the presence – whether for use as an ingredient or a processing aid - of any of the 14 major allergens listed in Annex II to the Regulation. The ways in which this mandatory information can be presented for prepacked food and non-prepacked food is explained later in this guidance. However, in both cases it should be noted that in accordance with Articles 12 and 13 of EU FIC, the mandatory information should be easily accessible, in a conspicuous place, easily visible and clearly legible. Information should be indelible (permanent) where appropriate, for example on food labels where it needs to withstand handling. The information should not be hidden, obscured, detracted from or interrupted by other written or pictorial matter or any other intervening material.

The fourteen allergens (Annex II allergens)

20. The 14 allergens listed in Annex II (as amended by Commission Delegated Regulation No. 78/2014) are recognised across Europe as the most common ingredients or processing aids causing food allergies and intolerances. If there is a food product which contains or uses an ingredient or processing aid (such as wheat flour used to roll out dough made from rye flour) derived from one of the substances or products listed in the Annex II, it must be declared, by the FBO to the consumer.

The Annex II allergens are:

- Cereals containing gluten namely wheat (such as spelt and Khorasan wheat), rye, barley, oats and their hybridised strains and products thereof, except:
 - a) wheat based glucose syrups including dextrose
 - b) wheat based maltodextrins
 - c) glucose syrups based on barley
 - d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin
- Crustaceans and products thereof (for example prawns, lobster, crabs and crayfish)

- Egg and products thereof
- Fish and products thereof, except:
 - a) fish gelatine used as carrier for vitamin or carotenoid preparations
 - b) fish gelatine or Isinglass used as a fining agent in beer and wine
- Peanuts and products thereof
- Soybeans and products thereof, except:
 - a) fully refined soybean oil and fat
 - b) natural mixed tocopherols (E306), natural D-alpha tocopherols, natural D-alpha tocopherol acetate and natural D-alpha tocopherol succinate from soybean sources
 - c) vegetable oils derived phytosterols and phytosterol esters from soybean sources
 - d) plant stanol ester produced from vegetable oil sterols from soybean sources
- Milk and products thereof (including lactose), except:
 - a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin
 - b) lactitol
- Nuts (namely almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistachio nut and Macadamia nut (Queensland nut)) and products thereof except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin
- Celery and products thereof
- Mustard and products thereof
- Sesame seeds and products thereof
- Sulphur dioxide and/ or sulphites at concentrations of more than 10mg/kg or 10mg/L (litre) in terms of the total SO₂ which are to be

calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers

- Lupin and products thereof
 - Molluscs and products thereof (for example mussels, clams, oysters, scallops, snails and squid)
21. The use of icons or symbols to indicate the presence of allergens is permitted as long as it is accompanied words and numbers to ensure uniform consumer understanding and to avoid misleading the consumer. Currently there is no single agreed set of icons or symbols across Europe for indicating the presence of allergens in prepacked and non-prepacked foods.

Exemptions from allergens declaration

22. The EU FIC requires the presence of allergens in the final foodstuff to be declared. Some ingredients made from the Annex II foods will not cause an allergic reaction because they have been highly processed (for example fully refined soya oil or wheat glucose syrups). This is because the allergen/protein has been removed and the product has been assessed by the European Food Safety Authority (EFSA) as not possessing an allergenic risk to the consumer.
23. Substances derived from an allergenic ingredient, which have been specifically exempted from declaration under Annex II (e.g. wheat glucose syrup), do not need to be declared.
24. In the case of wine and wine fining agents derived from egg and milk, EU Regulation No. 579/2012 will need to be considered. In determining whether egg and milk fining agents are still present in wine, they should not be found at the limit of detection (<0.25mg per litre) as indicated in EU Regulation No. 579/2012. Where egg or milk fining agents are not detected at these levels, they are exempt from the allergen labelling requirements.

PART 1: Guidance for businesses providing prepacked food

- For food manufacturers, packers, retailers and online or catalogue stores

Prepacked food

25. The following section provides guidance and examples of compliance with EU FIC provisions specific to allergen labelling for prepacked foods. This is based on the following articles:

- Article 9 on the list of mandatory particulars
- Article 13 on the presentation of mandatory particulars
- Article 19 on the omission of the list of ingredients
- Article 21 on labelling of certain substances or products causing allergies or intolerances
- Article 36 on applicable requirements relating to the provision of voluntary food information

26. Individuals who are not food businesses and occasionally provide food, for example at charity events or voluntary cake sales, do not need to follow these requirements.

List of mandatory particulars (Article 9)

27. Below, you will find guidance on the scope of each allergenic ingredient captured in Annex II of the Regulation and how the allergens should be emphasised in the ingredients list. The voluntary use of signposting to direct consumers where allergen information is found and emphasised is permitted. Details on signposting can be found in British Retail Consortium (BRC) / Food and Drink Federation (FDF) guidance www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf

Cereals containing gluten

28. The Regulations (Annex II to EU Regulation No. 1169/2011 as amended by Commission Delegated Regulation (EU) No.78/2014) define these as: wheat (such as spelt and Khorasan wheat), rye, barley and oats or their hybridised strains. Spelt and Khorasan are types of wheat, which are not suitable substitutes for people with coeliac disease and/or wheat allergy.

29. Cereals containing gluten will be declared in the ingredients list using the specific name of the cereal, i.e. wheat (such as spelt or Khorasan), rye, barley or oats. Where 'spelt', 'Khorasan' and 'Kamut' have been used; the inclusion of a specific reference to wheat would be required; for example 'spelt (**wheat**)' or 'Khorasan **wheat**' and 'Kamut (**wheat**)'.
30. The voluntary inclusion of gluten within the ingredients list following the mandatory declaration of a cereal containing gluten is possible. However, the regulation requires that it is the cereal that should be emphasised, rather than the gluten; for example '**barley** (gluten)'. When using a signpost to allergen information, indicating the presence of cereals containing gluten is also permitted as outlined in the BRC/FDF guidance document.
www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf
31. Where foods have been voluntarily labelled as 'gluten free', they must meet the requirements set in Commission Regulation No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. Guidance on the specific requirements for 'gluten free' labelling can be found on www.food.gov.uk/business-industry/allergy-guide/gluten. Ingredients which are or have been derived from cereals containing gluten will need to be emphasised within the ingredients list. This will make clear for those with an allergy to specific cereals to avoid such food; for example: 'Codex **wheat** starch'; '**barley** malt extract'.

Crustaceans

32. The rules do not name any specific species of crustaceans which means all types of crustaceans are included (for example lobster, crab, prawns and langoustines).
33. Labelling of crustaceans and products made from them need to have a clear reference to the Annex II food; for example 'prawns (**crustaceans**)', 'crayfish (**crustaceans**)', 'lobster (**crustaceans**)' shrimp paste (**crustaceans**).

Eggs

34. The rules do not name any species of eggs, because 'eggs' refers to eggs from all birds, for example from laying hens as well as eggs from ducks, quails, geese, gulls and guinea fowl. Therefore all eggs need to be declared when used as an ingredient or a processing aid, unless exempt (see p11-12 for exemptions).

Fish

35. The rules do not name any species of fish because 'fish' means all species of fish and fish products. The generic terms provisions allow the generic name 'fish' to be used in an ingredient list only where there is no specific reference to a common fish species name on the label, for example fish stock.
36. Labelling of fish ingredients or products need to have a clear reference to the Annex II food; for example, 'cod (**fish**)', 'salmon (**fish**)', 'tilapia (**fish**)', unless exempt (see p11-12 for exemptions).

Peanuts

37. While peanuts may also be commonly referred to as groundnuts (which can be confused with ground/powdered nuts such as almonds or a mix of nuts and peanuts) or monkey nuts, the term 'peanuts' should be used for products or ingredients made from them for allergen labelling purposes, as this is the term specified in Annex II of EU FIC.
38. Both refined and unrefined peanut oil have to be labelled with reference to peanut.

Soybeans

39. Terms such as 'soya' or 'soy' are sufficient to indicate the soybean origin. However less common terms such as tofu or edamame may not be recognised as originating from soya and its clear presence need to be indicated for soya products or derivatives. e.g. 'tofu (**soya**)' or 'edamame (**soya**)' unless exempt (see p11-12 for exemptions).

Milk

40. The rules do not name the animal origin of milk because the word 'milk' includes milk from mammals such as cow, sheep, goat, and buffalo etc. It should be noted that all mammalian milk proteins have a similar structure and if someone has an allergy or intolerance to cows' milk, they are likely to be allergic or intolerant to other mammalian milk. Therefore all milk and milk products (including lactose) need to be declared when used as an ingredient or a processing aid unless exempt (see p11-12 for exemptions).
41. Milk products such as cheese, butter, fermented milk and cream do not have to have an ingredients list, where no other ingredients have been added other than lactic acid, food enzymes and microbiological cultures and (in the case of cheese) salt. In order to ensure that consumers still receive the information they

need to clearly identify the presence of milk in such cases, the following advice may be applied. The use of sales names such as 'cheese', 'butter', 'cream' and 'yoghurt' is considered to refer clearly to the milk because legally these products can only be made from mammalian milk (EU Council Regulation No. 1308/2013 on Dairy designations). In such cases, further reference to 'milk' is not necessary because the Dairy designations protect such products. Therefore, cheese, butter, cream and yoghurt can be emphasised within the ingredients to demonstrate the presence of a milk product. The British Retail Consortium (BRC) and Food and Drink Federation (FDF) guidance provides best practice advice on this area and a literal interpretation of the EU FIC where all milk products have a clear reference to milk regardless of whether it is a protected term or not.

www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf

42. However, the information should make a clear reference to milk in the case of less familiar milk products used as ingredients (e.g. fromage frais, Mascarpone, Cantal, Quark) or products being sold under a name which does not clearly refer to milk. Components derived from milk, such as lactose, casein and whey, should be declared with a clear reference to milk e.g. 'whey (**milk**)'.

Nuts

43. The rules list these as: almond, hazelnut, walnut, cashew nut, pecan nut, Brazil nut, pistachio nut, macadamia nut or Queensland nut and products made from these nuts. The type of nut should be listed and emphasised in the ingredients panel. Other types of nuts, and other foods which are not nuts (even though they are called nuts i.e. chestnuts, pine nuts and coconut), are not named in the rules. Chestnuts and pine nuts are also known to cause allergy in some people, but are not required to be listed under these rules.
44. Where ingredients or processing aids derived from nuts have been used, the ingredient should be indicated with a clear reference to the nut; for example 'flavourings (**almond**)' unless exempt (see p11-12 for exemptions).

Celery

45. This term is used generically in EU FIC to refer to stick celery and celery root/tuber (also often known as celeriac). However, the term refers to any part of the celery plant and other forms that originate from it, such as celery leaf, celery root, celery seeds, celery oil, celery salt, celery spice, celery seed oil and celery seed oleoresin (an oil / resin extract from celery).

Mustard

46. This term refers to the mustard plant and other products which originate from it, such as leaves, sprouted seeds, mustard flour, table mustard, mustard oils, mustard seed oils and mustard oleoresins. The appropriate terms should be used in labelling. The rules do not name any particular species of mustards and therefore should be applied to all types of mustard.

Sesame

47. This term refers to sesame seeds, ground sesame powder and sesame oil. Products derived from sesame seeds, such as tahini, should be clearly labelled with a reference to sesame e.g. 'tahini (**sesame**)'. The rules do not name any particular species of sesame seeds and therefore should be applied to all.

Sulphur dioxide and/ or sulphites at levels above 10mg/kg or 10 mg/litre

48. This requirement relates to products or ingredients that have had sulphur dioxide and/ or sulphites intentionally added for example when it has been used as a preservative.
49. The labelling rules apply to sulphur dioxide and/ or sulphites that have been deliberately added in the preparation of the food or have been added to an ingredient used in a preparation of the food. The rules require sulphur dioxide and/ or sulphites to be labelled when present above 10mg/kg or 10mg/litre (calculated in terms of the total sulphur dioxide (SO₂)) in the finished product as consumed, i.e. prepared according to the manufacturer's instructions. The method of analysis for sulphur dioxide/sulphites cannot differentiate between those naturally present in the food or added as a preservative. Where sulphur dioxide and/ or sulphite based preservatives (even as carryover in an ingredient) have been used and the levels in the finished product are above 10mg/kg or 10mg/litre, it will need to be declared on the label.
50. Under general EU food labelling legislation, where sulphur dioxide and/ or sulphites have been added and have a technological function in the finished product, the function and the name and/or e-number of the additive should be included - for example: 'Dried Apple, (Preservative: **sulphur dioxide**) - however if only the E number is provided a clear reference to the allergen must be provided so it is easily understood by the consumer. Under allergen labelling legislation, when sulphites are present at above 10 mg/kg/litre in the finished

product, whether or not they have a technological function, a clear declaration of sulphites and/ or sulphur dioxide is always required.

EXAMPLE

51. The term 'sulphites' (or 'sulfites') may also be used as a generic term for this ingredient. Furthermore, depending on the particular sulphite present, the chemical name may be used with the sulphite element emphasised, for example, 'sodium metabisulphite'.

52. References to sulphur dioxide and/ or sulphites, which are used and found present in the finished product (ready for consumption or reconstituted according to manufacturers' instructions) at less than 10mg/kg or 10mg/litre is not required.

Lupin

53. The term lupin is used generically in EU FIC to refer to both lupin seed and products from it such as lupin flour. The appropriate terms should be used in labelling. The rules do not name any particular species of lupin and therefore should be applied to all.

Molluscs

54. The rules do not name any species because 'molluscs' includes all types of mollusc (for example oyster, squid, cockles, mussels, winkles and scallops as well as land molluscs like snails).

55. Labelling of mollusc ingredients and products derived from molluscs need to have a clear reference to the Annex II food; for example, 'mussels (**mollusc**)', 'octopus (**mollusc**)', 'oyster (**mollusc**)'.

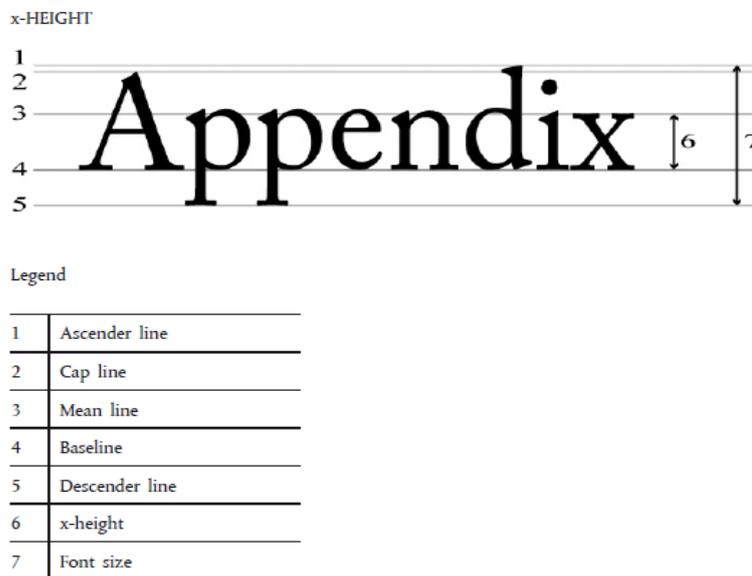
Presentation of mandatory particulars (Article 13)

56. Mandatory information is the information you have to provide for the food you sell. All written mandatory allergenic information should be easily visible, clearly legible and not obscured in any way. Mandatory information should be not hidden for example under a flap or across a fold or crease, detracted from or

interrupted by any other written or pictorial matter or any other intervening material.

57. Consider whether the mode of emphasis
- Is sufficiently visible
 - Is readable for those with visual impairments? For example consider individuals with colour blindness when using contrasting colours.
58. A minimum font size where the x-height (as illustrated in Annex IV of EU FIC) is 1.2mm or more should be used where labelling surface is 80cm² or more.
59. A minimum font size where the x-height is 0.9mm or more should be used where the labelling surface is less than 80cm². Figure 1 below illustrates how the x-height of the font used is measured.

Figure 1: How to measure x-Height of your font



60. Where the food packaging or container's largest surface area is less than 10cm² (e.g. a single portion sachet of sauce), the ingredients list can be omitted, provided that the ingredients information is provided by other means or made available at the consumer's request. In such cases, the presence of Annex II ingredients in the food must be indicated by the word 'contains...' followed by

the name of substance or product (e.g. Contains: celery, fish). The minimum font size rules also apply to other mandatory information as listed in Article 9 (1) of EU FIC. Please refer to Article 13 of EU FIC for further details.

Omission of the list of ingredients (Article 19)

61. Where the name of the product consists of a single ingredient (e.g. bag of peanuts or a box of eggs) and clearly refers to the presence of a substance or product causing allergies, further indication of the presence of the Annex II substance or product is not required. Therefore, in these examples, a bag of peanuts and a box of eggs would not need to declare the presence of peanut and egg respectively. However, where the name of the food is less familiar you may wish to include a contains statement; for example gingelly oil (contains sesame)

Labelling of certain substances or products causing allergies or intolerances (Article 21)

62. This specifies that mandatory information about the presence of the Annex II ingredients which cause allergies will need to be emphasised from the other ingredients within the ingredients lists by means of contrasting font, size, style or background colour. For example: 'INGREDIENTS: **Oatmeal**, sunflower oil, prawn (**crustacean**)'.
63. The FBO has flexibility in deciding which mode of emphasis to use to declare the presence of allergens.

EXAMPLE

Use an allergy advice statement on the product label to explain how allergens are emphasised within the ingredients list. For example: 'Allergy advice: for allergens, see ingredients in **bold**' or 'Allergy advice: for allergens, including cereals containing gluten, see ingredients highlighted in **blue**'.

64. The source of allergens for each ingredient needs to be declared even if there are several ingredients from the same allergenic food. For example:

Partially Reconstituted Skimmed **Milk** Concentrate, Sugar, Sunflower Oil, Whey Powder (**milk**), Dextrose, Emulsifier (Mono- and Di-Glycerides of Fatty Acids), Flavouring, Stabilisers (Guar Gum, Sodium Alginate), Colours (Beetroot Red, Beta-Carotene).

65. If the name of an ingredient partly includes the Annex II allergen in a single word, then the name of the ingredient corresponding to the Annex II food can be emphasised. For example: 'wheatflour' is '**wheatflour**' or to emphasise the entire name '**wheatflour**').
66. Where an ingredient comprises of several words (such as 'skimmed milk powder' and 'egg white') then only the Annex II food should be emphasised (in these examples, 'skimmed **milk** powder' and '**egg** white').

EXAMPLE

Where ingredients used in a food product contain added sulphur dioxide and/ or sulphites, carry over presence will need to be considered. Where the level of added sulphur dioxide /sulphite in the finished product is >10mg/kg, the presence will need to be declared in ingredients containing added sulphur dioxide and/ or sulphites and contributing to the end level

67. Where foods are sold under a less common name, due to appellation, trade name, foreign cuisine etc., it could be difficult to tell whether they contain any of the Annex II products/substances (e.g. 'gingelly oil (**sesame**)', 'ghee (**milk**)', 'edamame beans (**soya**)'). In such cases, further qualification is required.

Food products without ingredients lists

68. Some foods do not require an ingredients list, such as alcoholic drinks with more than 1.2% by volume of alcohol (see Article 16 (4) of EU FIC). However, they will need to declare the presence of any substances or products derived from the Annex II list which is present and not clear from the name of the food. For example, a bottle of wine should have a statement such as: 'Contains: sulphites' if the finished product contains sulphites at more than 10mg/litre. The presence of egg and milk fining agents will also need to be declared if found present at 0.25mg/litre and above.

EXAMPLE

Allergen(s) within a 'contains' statement on products without ingredients lists do not need to be emphasised however, you can voluntarily choose to emphasise the allergens to make clear their presence in a product (e.g. 'Contains: **sulphites**').

Applicable requirements – voluntary information (Article 36)

69. Where an ingredients list is provided, the EU FIC does not permit the voluntary use of allergen advisory statements such as: 'Contains: wheat, egg and milk' to repeat mandatory allergen ingredients information. Information about allergens as ingredients can only be presented in the mandatory format (i.e. emphasised within the ingredients list). This is to ensure that information is presented in a single and consistent format across food products.

Voluntary use of precautionary allergen labelling to indicate the unintentional presence of allergen

70. FBOs voluntarily use precautionary allergen labelling such as 'may contain' or 'not suitable for...' to communicate the risk of the unintentional presence of an allergen (e.g. milk, egg, nuts) in a food product due to the allergen entering the product accidentally during production, through cross-contamination. The voluntary use of such precautionary allergen labelling is still permitted; the basis for this is contained within Article 14 of EU Regulation No.178/2002 (General Food Law).
71. The use of the generic term 'may contain nuts' to cover both nuts and peanuts is permitted if the risk of contamination is from both foods. There is no need to provide details of specific nuts under this type of voluntary labelling.
72. The application of precautionary allergen labelling should only be made after a thorough risk assessment has been performed and there is considered to be a real risk to the food allergic or food intolerant consumer. The use of precautionary allergen labelling, when there is not a real risk, could be considered to be misleading. For detailed best practice guidance on allergen management and the voluntary application of precautionary allergen labelling, please see:

Food Standards Agency best practice guidance on:

www.food.gov.uk/sites/default/files/multimedia/pdfs/maycontaininguide.pdf

or

Food Drink Europe (FDE) guidance on:

www.fooddrinkeurope.eu/uploads/press-releases_documents/temp_file_FINAL_Allergen_A4_web1.pdf

Distance selling (Article 14)

73. FBOs selling prepacked foods through distance selling need to make the same level of information on allergens available for example on their website or in their catalogue, as when the food is bought from a retail environment¹. This is to ensure that the mandatory allergen information is available before the purchase is concluded and at the point of delivery. Telephone numbers provided by FBOs which enable consumers to obtain oral allergen information over the telephone, must not be at an additional cost (in other words the calls must be free or non-chargeable within standard rate call plans). The distance selling rule to provide information before the purchase is concluded, does not apply to prepacked foods sold through vending machines. Where multiple items are contained within a gift box or hamper of food, mandatory food information such as allergen ingredients information should be provided on materials that support this sale.

¹ For distance sales of prepacked food you are also required to provide other mandatory information as listed in Article 9 with exception of Article 9 (1) (f)

PART 2: Guidance for businesses providing non-prepacked and prepacked for direct sale foods

- For restaurants, cafés, fast food outlets, delicatessens, butchers, bakeries, institutional and other types of caterers.

Non-prepacked food

74. The information below provides guidance and best practice examples on the provision of allergen ingredients information for non-prepacked (such as meals served in a restaurant or café) and includes prepacked for direct sale foods (such as meals prepacked in a canteen for consumption on or off the premises, cheese or meat sold loose from a delicatessen counter, bread or pies sold at bakeries or meat and meat products at butchers and packed at the consumer's request). All mandatory allergen ingredients information (Article 9 (1) (c)) should be available and easily accessible for the consumer. The rules for non-prepacked food came into effect on 13 December 2014. Businesses should review ingredients information for foods provided by them and ensure that their suppliers provide them with the necessary information to meet their obligations. The requirements are based on the following articles:

- Article 8 on responsibilities
- Article 9 on the list of mandatory particulars (see p11-12 for list of 14 allergens)
- Articles 12 and 13 on availability and presentation of mandatory particulars
- Article 21 on labelling of certain substances or products causing allergies or intolerances
- Article 44 on national measures for non-prepacked food
- Article 14 on distance selling

75. Individuals who are not food businesses, for example those who occasionally provide food at charity events or voluntary cake sales, do not need to follow these requirements. If you are a charity or community food provider and unsure whether you should be registered as a food business, you can speak to your local authority's environmental health department. Further guidance is also available in the FSA's guidance document 'Community and charity food provision - guidance on the application of EU food hygiene law' which is available on the FSA's web site:

www.food.gov.uk/enforcement/enforcework/food-law/guidance-enforcement/community-hall-guidance

76. For detailed best practice guidance on allergen management for non-prepacked food, please see Food Standards Agency Scotland's Cooksafe - Food Safety Assurance Scheme: www.foodstandards.gov.scot/cooksafe

(Please note responsibility for CookSafe will be transferred to Food Standards Scotland after 1 April 2015)

Responsibilities (Article 8)

77. Every FBO in the food supply chain has to take responsibility for ensuring that the allergen information they provide is accurate. They must not supply food which they know or presume to be non-compliant with the law.
78. Food businesses supplying food to other food businesses, that is not intended for the final consumer and / or not intended for mass caterers, must ensure that business to business sales of food (prepacked and non-prepacked) are accompanied with sufficient information to enable subsequent food businesses to meet their responsibilities. FBOs who do not affect food information must not supply food which they know or presume to be non-compliant. FBOs are responsible for ensuring compliance with the provisions relevant to their activities and verify that those requirements are met. This applies to manufacturers, suppliers and the caterers.

Presentation of mandatory allergen information (Articles 9, 12, 13 and 21)

79. Allergen information for non-prepacked food can be communicated through a variety of means to suit the business format of the FBO. The requirement is to provide information about the use of allergenic ingredients in a food. The provision does not require food businesses to provide a full ingredients list. Where food business choose for this information to not be provided upfront in a written format (for example allergen information on the menu or foods sold by a butcher or delicatessen), the food business should use clear signposting to direct the customer to where this information can be found, such as asking members of staff. In such situations there must be a statement that can be found on food menus, chalkboards, food order tickets, food labels or webpages (see Regulation 5 (4) of the Food Information Regulations 2014).

80. In the drive-through (or drive-thru) scenario, signage that indicates that oral information is available through a member of staff elsewhere on the premises is permitted.
81. All mandatory allergen information, on menus or signpost statements to where it could be found, should be easily accessible and visible, and clearly legible to the final consumer regardless of whether they have a food allergy or not.

EXAMPLE

Upfront signposting to where allergen information will be found could be presented as a statement such as:

'Food Allergies and Intolerances: Before you order your food and drinks please speak to our staff if want to know about our ingredients'

82. Allergen ingredients information for cereals containing gluten and nuts need to declare the specific cereal or the nut as listed Annex II. This is because there are people who have an allergy to a specific cereal such as wheat allergy as well as those with gluten intolerance. This is also the case for those with nut allergies.
83. No specification needs to be provided for fish, molluscs or crustaceans when used as ingredients in a dish as there is no designated list for this group within the Annex II list.
84. Allergen ingredients information should be made available for the entire dish as served. Allergen information can be provided in a variety of ways.
85. Where food is provided through a buffet format, the allergen information should be provided for each food item separately.

EXAMPLE

Allergen information could be provided as a 'contains' statement, for example 'Chicken Tikka Masala (contains: milk, nuts (almond))'. Another method could be the use of a chart, such as the example below:

Dish	Cereals containing gluten	Crustaceans	Eggs	Fish	Peanuts	Soyabeans	Milk	Nuts	Celery	Mustard	Sesame	Sulphites	Lupin	Molluscs
Chicken korma							✓	✓ Almond						
Seafood risotto		✓		✓			✓		✓					✓
Lincolnshire Sausage and mustard mash	✓ Wheat						✓		✓	✓				
Special fried rice	✓ Wheat		✓			✓					✓			
Lemon cheesecake	✓ Wheat, oats		✓				✓	✓ Almond						

86. Where food is placed on the market by a food business free of charge (such as testers and samples, canapés served at events) or as complimentary snacks or meals (such as a plate of biscuits or chocolates at hotels, airline meals, meals served at events), information about allergenic ingredients must be provided. This should be provided in writing or signposted to where it could be obtained for example through a member of staff on a label, menu or ticket.

EXAMPLE

Allergen information for the components within a dish could voluntarily be provided, to give a better service and choice for the customer.

For example: BBQ Chicken Burger and coleslaw (Chicken: **wheat, fish, celery**; BBQ sauce: **celery, fish**; Bap: **wheat, eggs** and **sesame**; Coleslaw: **egg, celery, mustard**).

If a customer had an allergy to mustard for example, the dish could be served without the coleslaw.

National measures (Article 44)

87. Given the practical difficulties some businesses may face, such as ensuring that written menus are kept up-to-date and displaying accurate information regarding allergenic ingredients used in products, FBOs have flexibility to provide allergen information for non-prepacked food orally. In such cases customers must be able to obtain information from members of staff.
88. However, businesses adopting this approach will need to ensure that there is a written notice, menu, ticket or label that is clearly visible, at the point that the customer chooses their food, to indicate that allergen information is available from a member of staff.
89. FBOs are recommended to have a system in place to ensure that when allergen information is provided orally to consumers, it is supported by that information being available to staff and others in a recorded form (in writing for example) to provide consistency, accuracy and verifiable safety procedures.

EXAMPLE

To ensure that consistent allergen information is provided, the FBO should consider using a system where staff direct queries to a nominated person(s).

To ensure that oral information is verifiable, ingredients information can be contained on a chart, in a recipe book or on ingredients information sheets, which staff can easily refer to.

Distance selling (Article 14)

90. FBOs selling non-prepacked food through distance selling (e.g. such as food takeaway businesses which offer purchase through telephone/ internet) will need to ensure that mandatory allergen information is available to the consumer:

- before the purchase is concluded; and
- at the point of delivery.

The allergen information should be held in written form by the business and available in written form at some point between a consumer placing the order and taking delivery of it.

91. Whatever the chosen method of presentation, the FBO must always ensure that the allergen information is current and accurate.

92. The allergen information should be provided without any supplementary costs being charged to the customer by the FBO (e.g. premium line numbers).

EXAMPLE

Ways of providing allergen information at the time of order include:

- the customer is signposted to where the information can be obtained in writing (e.g. an online menu); or
- staff provide the allergen information orally by telephone whilst referring to the written information.

To ensure that current and accurate allergen information is provided, the food business could ask the customer if allergen information is required before the order is taken on the telephone or online.

Ways of providing written allergen information at the time of delivery include:

- placing stickers on food containers to clearly identify food and allergenic ingredients used in that food (e.g. **Chicken satay**: 'Contains: wheat, soy, fish, peanut'); or
- a menu is provided with the order which allows the customer to clearly

identify allergenic ingredients in the food, along with clear names, or other appropriate cross-references on food containers;

- written allergen information is presented to the customer, by the member of staff from the business delivering the food together with a means to clearly link the written information to each food item.

93. In distance sales involving a third party 'broker' (such as online aggregators for take away businesses) the third party and the FBO supplying the food to the consumer must work together to ensure that the required allergen information is provided to the consumer, and that the consumer is clear on how to obtain the allergen information. The FBO preparing and providing the food will be best placed to know the allergen content and provide the information to consumers and is therefore ultimately responsible for the allergen information given to the consumer.

Enforcement of the measures

Local authority responsibilities

94. In the UK, authorised food officers at Local Authorities have responsibility for official controls relating to allergen rules. As allergen rules did not previously cover non-prepacked food (prior to EU FIC), some changes to food enforcement responsibilities at local level have been made.
95. In practice, the new allergen requirements for non-prepacked foods mostly impact on the food service/catering sector and retail businesses selling non-prepacked foods such as butchers, bakers, market stall holders and delicatessens.
96. In England, where there is a dual enforcement responsibility in some areas, the first tier (County Councils) are under a duty to enforce (Regulation 9 (1) Food Information Regulations 2014 (FIR) SI 2014/1855) and second tier councils have the power to enforce (Regulation 9 (2) Food Information Regulations 2014). Although there is no need for arrangements to be made to give powers to food hygiene enforcement officers in second tier councils, authorised food officers are encouraged to discuss and reach an understanding on how to enforce allergen requirements at a local level.

Penalties and offences

97. Failure to comply with the requirements of the provisions of the EU FIC set out in Regulation 10(2) of the FIR (SI 2014/1855) and corresponding Regulations in Wales, Scotland and Northern Ireland on the labelling of allergenic ingredients is a criminal offence and may result in a criminal prosecution being brought against an FBO. This position is the same in relation to a failure to comply with Regulation 5(5) of the FIR relating to the provision of allergen information for non-prepacked foods etc. in a manner other than one provided for in EU FIC.
98. A person found guilty of an allergens offence under FIR 2014 will be liable to a fine. Section 85 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012 has come into effect meaning that fines in the legislation that had a £5,000 limit have changed the maximum fine into a fine of any amount. The amount of the fine would be up to the Magistrates to decide on a case by case basis. Please note that Section 85 of the 2012 Act only extends to England and Wales.

Glossary of terms used

Food Allergen: This is the substance in a food that can cause an allergic reaction. Allergens are normally proteins and in some people, the immune system thinks allergens are foreign or dangerous. The immune response to these allergenic proteins is what leads to allergic reactions. The EU states 14 specific foods which are of public health importance (most potent and prevalent food allergens in Europe) which are listed in Annex II to the EU FIC.

Distance selling: This refers to the selling and buying of goods or services (for purposes of these guidance notes – prepacked, prepacked for direct sale and non-prepacked foods) without direct face to face contact; for example, selling food by internet (internet shopping, online takeaway aggregators etc.), mail order, telephone or television.

Final consumer: This is defined in Article 3 (18) of EU Regulation No.178/2002 as 'the ultimate consumer of a foodstuff who will not use the food as part of any business operation or activity'. The final consumer will generally be the individual who will be eating or drinking the food or drink provided by the food business.

Food allergy: An adverse reaction to a food that involves the immune system and can be a potentially life threatening condition. Symptoms can appear within minutes, or up to several hours after a person has eaten a food they are allergic to. There is no cure for food allergy. An allergic individual must avoid the food which makes them ill.

Food business operator (FBO): This is defined in EU Regulation No. 178/2002 (Article 3(3)) (General Food Law) as 'the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control'. A food business (as referred to in Article 3(2)) is also defined in the same regulation, as 'any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food'.

Food intolerance: Most food intolerances do not involve the immune system and are generally not life-threatening. However, they can make someone feel very ill or affect their long-term health. Examples of food intolerance include lactose and gluten intolerance.

Mass caterer: This is defined in Article 2 (2)(d) of EU FIC as 'any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer'.

Non-prepacked foods:

- In a physical retail environment this is likely to apply to foods which are sold loose from a delicatessen counter (e.g. cold meats, cheeses, quiches, pies and dips), fresh pizza, salad bars, bread sold in bakery shops, meat from butchers, pick and mix confectionery (including individually wrapped sweets and chocolates), etc.
- In a catering environment this is likely to apply to foods which are not sold prepacked, for example food from a takeaway, or meals served in a canteen or a restaurant.

Prepacked foods: This refers to any food put into packaging before being offered for sale for example a bar of chocolate, a sealed packet of crisps, a jar of sauce or a can of soup. All the following must apply:

- the food is either fully or partly enclosed by the packaging;
- the food cannot be altered without opening or changing the packaging;
- the product is ready for sale to the final customer or to a mass caterer.
(Adapted from the definition in Article 2 (2)(e) of EU FIC).

Prepacked foods for direct sale: This applies to foods that have been packed on the same premises from which they are being sold. Foods prepacked for direct sale are treated in the same way as non-prepacked foods in EU FIC's labelling provisions. For a product to be considered 'prepacked for direct sale' one or more of the following can apply:

- It is expected that the customer is able to speak with the person who made or packed the product to ask about ingredients.
- Foods that could fall under this category could include meat pies made on site and sandwiches made and sold from the premises in which they are made.

References and Resources

- Further advice on food allergen labelling is available on the Agency's website: www.food.gov.uk/policy-advice/allergyintol/label/
- FSA allergen resources at: www.food.gov.uk/allergen-resources
- Advice for SMEs on prepacked food can be found here: www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/allergy-labelling-prepacked.pdf
- Advice for SME's on non-prepacked food and the Think allergy poster can be found here: www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/loosefoodsleaflet.pdf and www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/thinkallergy.pdf
- Advice for consumers on the new allergen labelling, allergen information when eating out and the chef cards can be found here: www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/allergy-leaflet.pdf and www.food.gov.uk/sites/default/files/allergy-chef-cards.pdf
- FSA has produced free online training modules to help enforcement officers and businesses understand food allergen labelling and labelling in general under the EU FIC. Free online allergy training can be found here: <http://allergytraining.food.gov.uk/>
Free online training about the Food Information Regulation as a whole can be found here: <http://labellingtraining.food.gov.uk/>
- Food Standards Agency Scotland produced an online resource called Cooksafe which contains detailed steps on managing allergen risks and communicating allergen information to staff and customers. Please note responsibility for CookSafe will be transferred to Food Standards Scotland after 1 April 2015. Cooksafe can be found on: www.foodstandards.gov.scot/cooksafe
- British Retail Consortium (BRC) and Food and Drink Federation (FDF) have produced best practice guidance to help those labelling prepacked foods and can be found on: www.brc.org.uk/downloads/Guidance%20on%20Allergen%20Labelling.pdf

Relevant legislation:

- Commission Delegated Regulation (EU) No.78/2014 amending Annex II and III to Regulation (EU) No. 1169/2011 (EU FIC) : <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:027:0007:0008:EN:PDF>
- Commission Regulation (EU) No. 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:016:0003:0005:EN:PDF>
- EC Regulation 178/2002 (General Food Law Regulation): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>
- EU Regulation No. 579/2012 labelling and presentation of wine sector products www.fsai.ie/uploadedFiles/Legislation/Food_Legislation_Links/Alcohol/Reg579_2012.pdf
- EU Regulation No. 1169/2011 on the provision of food information to consumers (EU FIC): <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>
- Food Safety Act 1990 and subsequent amendments: www.legislation.gov.uk/ukpga/1990/16/contents ; Food Safety (NI) Order 1991 in Northern Ireland and subsequent amendments: www.legislation.gov.uk/nisi/1991/762/contents/made
- Regulation (EU) 1308/2013 establishing common organisation of the markets in agricultural products ('Dairy Designations') <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:347:0671:0854:EN:PDF>

Review

This guidance will be reviewed on 1 July 2016. We welcome any comments/ feedback on this guidance. Please complete and return this [feedback questionnaire](#) .

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Food Standards Scotland

Email: enquiries@fss.scot

Food Allergy in the United States: Recent Trends and Costs

An Analysis of Private Claims Data

A FAIR Health White Paper, November 2017



Summary

Food allergy is a growing national health problem, affecting both children and adults. It is increasing in prevalence and its most dangerous consequence—the severe, potentially fatal reaction called anaphylaxis—is becoming more common. This analysis reports trends and patterns related to the extent and impact of food allergy and anaphylactic food reaction using data from FAIR Health, a national, independent, nonprofit organization that emphasizes transparency in healthcare costs and health insurance information. Among the findings from FAIR Health’s analysis of its database of billions of privately billed healthcare claims:

- From 2009 to 2016, the percent of claim lines with food allergy diagnoses compared to all of a state’s medical claim lines grew in many states.¹ For example, in 2016, the state with the highest percent was North Carolina, which had a relatively low percent in 2009.
- From 2007 to 2016, the increase in claim lines with food allergy diagnoses was greater in rural (110 percent) than urban (70 percent) areas—despite past evidence that food allergy is more common in urban areas.
- From 2007 to 2016, claim lines with diagnoses of anaphylactic food reactions rose 377 percent.
- Although food allergy is commonly thought of as a childhood condition, about a third (34 percent) of claim lines with diagnoses of food allergy from 2007 to 2016 were attributable to patients over 18 years old.
- In the period 2007-2016, claim lines with food allergy diagnoses were associated with boys more than girls during childhood (ages 0 to 18 years), but in adults the reverse was true: Food allergy claim lines were associated with women more than men.
- Anaphylaxis is typically regarded as a medical emergency, but in the period 2007-2016, most services (70 percent) provided to patients diagnosed with anaphylactic food reaction were rendered in an office setting, with only 2 percent specifically designated as occurring in an emergency room.
- Although laboratory services associated with diagnoses of anaphylactic food reaction increased 871 percent in utilization from 2007 to 2016, charges for those services increased 5,390 percent in the same period.
- The food allergy with the highest average costs and services per patient in 2016 was milk product allergy, which generally tends to be associated with the youngest patients (infants and toddlers) and with prescription formulas.

Background

In the United States and other parts of the developed world, food allergy has been growing in prevalence, though the precise rate of increase is unclear.² A systematic review of studies on food allergy in US children from 1988 to 2011 found an increase of self-reported food allergy of 1.2 percentage points per decade.³ The Centers for Disease Control and Prevention (CDC) stated in 2008 that the prevalence of

¹ Claim lines are the individual procedures or services listed on an insurance claim. In figures in this report not related to state-by-state analysis, “percent of claim lines” usually means the percentage that claim lines associated with a given diagnosis in a given year bear to the total claim lines with that diagnosis throughout a designated period.

² Joyce Irene Boye, “Food Allergies in Developing and Emerging Economies: Need for Comprehensive Data on Prevalence Rates,” *Clin Transl Allergy* 2, no. 1 (2012): 25; doi:10.1186/2045-7022-2-25.

³ Corinne A. Keet et al., “Temporal Trends and Racial/Ethnic Disparity in Self-Reported Pediatric Food Allergy in the US,” *Ann Allergy Asthma Immunol* 112, no. 3 (2014): 222-29.e3; doi:10.1016/j.anai.2013.12.007.

reported food allergy grew 18 percent among children from 1997 to 2007.⁴ Another CDC study found the increase in food allergy prevalence among children to be 50 percent from 1997-1999 to 2009-2011.⁵

Food allergy, a condition in which the immune system reacts to certain foods that are normally considered harmless, is not only bothersome and restricting; it also can result in severe morbidity and even mortality. Anaphylaxis, a severe, life-threatening allergic reaction that can be triggered by food or other allergens, accounts for 186 to 225 deaths per year in the United States.⁶ A study of pediatric emergency room visits and hospital admissions in Illinois due to anaphylaxis induced by food found that such visits and admissions grew annually by 29.1 percent from 2008 to 2012.⁷

Food allergy is more common in children than adults, but it is not restricted to children. Estimates of the proportion of children with food allergy range from approximately four⁸ to eight percent,⁹ and estimates of the proportion of adults with food allergy range from one¹⁰ to three percent.¹¹ Although some children outgrow some food allergies, there have been reports that children may be outgrowing them more slowly than in the past.¹²

A number of genetic and environmental risk factors for food allergy have been identified, but it remains uncertain why food allergy is increasing in prevalence.¹³ Greater awareness and detection of food allergy,¹⁴ decreases in exposure to microbes early in life, changes in how food is manufactured and alterations in the human microbiome may all play a role.¹⁵

To shed light on recent trends and patterns related to food allergy and anaphylactic food reaction in the American privately insured population, FAIR Health analyzed its database of over 24 billion privately billed healthcare procedures. The study included analysis of the prevalence of food allergy, as measured in geographic patterns (state-by-state and urban/rural), anaphylactic food reaction trends and demographic patterns (age and gender). It also included examination of the impact on the healthcare

⁴ Amy M. Branum and Susan L. Lukacs, *Food Allergy among U.S. Children: Trends in Prevalence and Hospitalizations*, NCHS Data Brief, no. 10; Hyattsville, MD: National Center for Health Statistics, 2008; <https://www.cdc.gov/nchs/data/databriefs/db10.pdf>.

⁵ Kristen D. Jackson, LaJeana D. Howie and Lara J. Akinbami, "Trends in Allergic Conditions among Children: United States, 1997-2011," NCHS Data Brief, no. 121; Hyattsville, MD: National Center for Health Statistics, 2013; <https://www.cdc.gov/nchs/data/databriefs/db121.pdf>.

⁶ American Academy of Allergy, Asthma & Immunology, "Death from Anaphylaxis Is a Reassuringly Unusual Outcome," December 13, 2013, <https://www.aaaai.org/global/latest-research-summaries/Current-JACI-Research/death-anaphylaxis>.

⁷ Ashley A. Dyer et al., "Pediatric Emergency Department Visits and Hospitalizations Due to Food-Induced Anaphylaxis in Illinois," *Ann Allergy Asthma Immunol* 115, no. 1 (2015): 56-62; doi:10.1016/j.anai.2015.05.006.

⁸ Branum and Lukacs, *Food Allergy among U.S. Children*.

⁹ Ruchi S. Gupta et al., "The Prevalence, Severity, and Distribution of Childhood Food Allergy in the United States," *Pediatrics* 128, no. 1 (2011): e9-17; doi:10.1542/peds.2011-0204.

¹⁰ Stacie M. Jones and A. Wesley Burks, "Food Allergy," *N Engl J Med* 377, no. 12 (2017): 1168-76; doi:10.1056/NEJMcp1611971.

¹¹ Leticia Tordesillas, M. Cecilia Berin and Hugh A. Sampson, "Immunology of Food Allergy," *Immunity* 47, no. 1 (2017): 32-50; doi:10.1016/j.immuni.2017.07.004.

¹² Jessica H. Savage et al., "The Natural History of Egg Allergy," *J Allergy Clin Immunol* 120, no. 6 (2007): 1413-17; doi:10.1016/j.jaci.2007.09.040.

¹³ Jessica Savage and Christina B. Johns, "Food Allergy: Epidemiology and Natural History," *Immunol Allergy Clin North Am* 35, no. 1 (2015): 45-59; doi:10.1016/j.iac.2014.09.004.

¹⁴ Jacob Kattan, "The Prevalence and Natural History of Food Allergy," *Curr Allergy Asthma Rep* 16, no. 7 (2016): 47; doi:10.1007/s11882-016-0627-4.

¹⁵ Jones and Burks, "Food Allergy."

system, as seen in places of service, most common procedure code categories, and costs and number of services per patient.

Methodology

FAIR Health analyzed private insurance claims associated with allergy diagnoses, evaluated claim characteristics (such as age and gender of patient and location of service) and examined procedure codes reported on the claims. Trends and patterns in utilization and costs were then identified. The claims-level analysis is a strength of the study. Claims reflect healthcare usage and the information provided on claims reflects the assessments of providers, whose training and experience make them better judges of health conditions than laypeople. The rest of this section describes the methodology in more detail.

Using the International Classification of Diseases (ICD-9-CM and ICD-10-CM) diagnostic codes reported on claims in the FAIR Health dataset, FAIR Health examined claims that were indicative of a food allergy (e.g., ICD-9-CM V15.01, Hx-peanut allergy, and ICD-10-CM Z91.010, peanut allergy) and anaphylaxis associated with a particular food (e.g., ICD-9-CM 995.64, anaphylactic reaction to tree nuts/seeds, and ICD-10-CM T78.00XA, anaphylactic reaction to other specific foods).

Although anaphylactic reaction to tree nuts/seeds (ICD-9-CM 995.64, ICD-10-CM T78.05XA, T78.05XD, T78.05XS) and anaphylactic reaction to crustaceans (ICD-9-CM 995.62, ICD-10-CM T78.02XA, T78.02XD, T78.02XS) are specifically segregated out within the International Classification of Diseases, their corresponding “history of” (Hx-) or diagnoses of the allergies are not. Tree nut/seed allergies are grouped into the ICD-9-CM Hx-other food allergy (V15.05) and ICD-10-CM other food allergy (Z91.018); crustacean allergies are grouped into the ICD-9-CM Hx-seafood allergy (V15.04) and ICD-10-CM seafood allergy (Z91.013).

Data were evaluated by stratifying them by gender, age, type of food causing the allergy or reaction and the location in which the service was performed, using a combination of the US Census Bureau’s classification categorizations, including the urban-rural data, and the FAIR Health geozip paradigm, which divides the United States into 493 separate geographic regions.

Analysis was conducted on CPT® codes¹⁶ (maintained by the American Medical Association [AMA]) and HCPCS Level II codes (maintained by the Centers for Medicare & Medicaid Services [CMS]), such as office or outpatient services established patient (E&M; e.g., CPT 99214, office outpatient visit, 25 minutes), immunology services (e.g., CPT 86003, allergen specific IgE quantitative or semi quantitative, each allergen) and allergy testing (e.g., CPT 95004, percutaneous tests with allergenic extracts).

The data were aggregated by a variety of key fields, including state, procedure code category (e.g., allergy testing, immunology services, office or outpatient services established patient), gender, age and year of service, to identify trends and patterns in utilization and cost by both charges and imputed allowed amounts.¹⁷ The data were evaluated with single and multiple variables to look for distinct trends and associations.

In the graphical representations below, the term “claim lines” refers to the individual procedures or services listed on insurance claims. (The terms “procedures” and “services” are used interchangeably in this report.) A single claim for one patient may have multiple claim lines. “Percent of claim lines” is the percent of all claim lines associated with a given grouping of diagnosis codes (e.g., codes associated with food allergy diagnoses) in a given time period (e.g., 2007-2016). All charges and allowed amounts are

¹⁶ CPT © 2016 American Medical Association (AMA). All rights reserved.

¹⁷ Imputed allowed amounts are estimates of the amounts typically negotiated between payors and providers.

based on data in the FAIR Health repository of claim records contributed by payors and administrators who insure or process claims for private insurance plans covering more than 150 million individuals.

Geographic Patterns

State-by-State Trends, 2009-2016

In 2016, the percent of claim lines with food allergy diagnoses compared to all medical claim lines that were submitted for a state in the FAIR Health dataset was higher in many states than it was in 2009. In the heat maps below, where dark green represents the lowest percent of claim lines with food allergy diagnoses and red the highest, there was a shift in many states from mostly dark and moderate green in 2009 (figure 1) to pale green, yellow and orange in 2016 (figure 2). For example, in 2009, North Carolina was a moderate green (relatively low percent of claim lines with food allergy diagnoses); in 2016, it was a bright red—in fact, it had the nation's highest percent of claim lines with food allergy diagnoses.

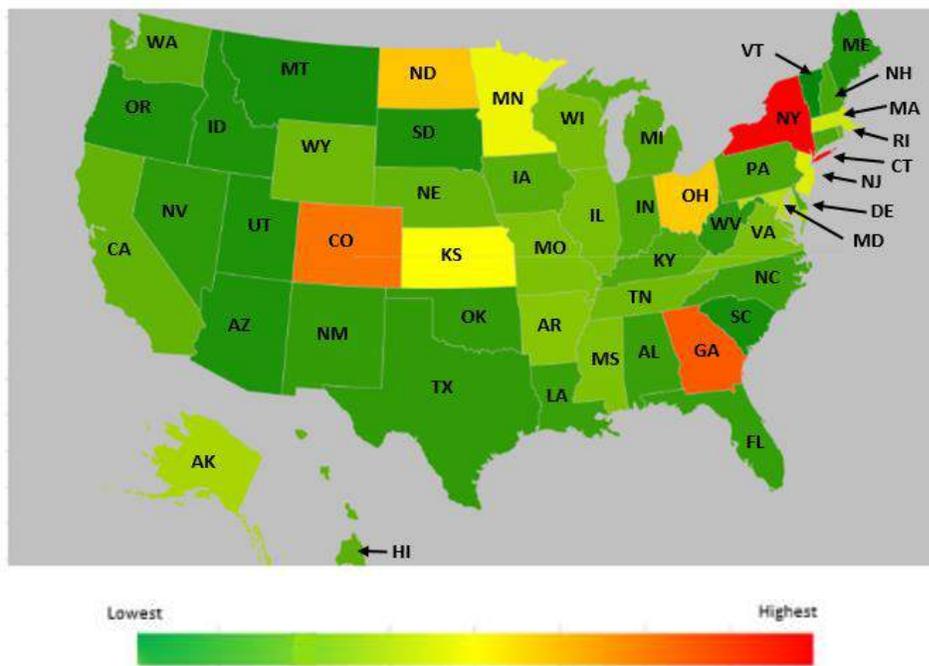


Figure 1. Percent of claim lines with food allergy diagnoses compared to all medical claim lines by state, 2009.

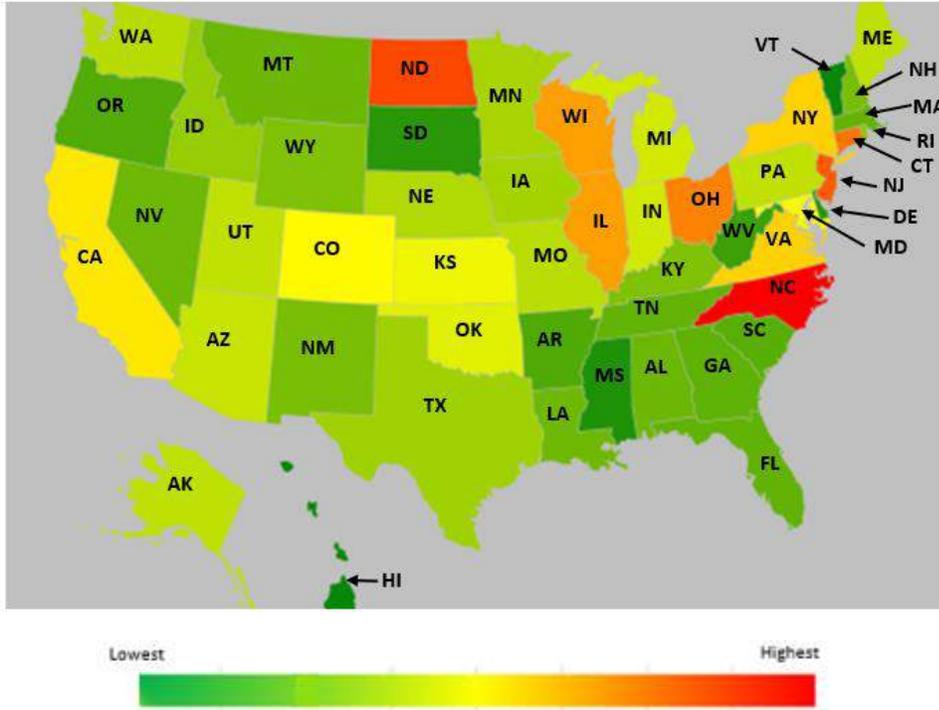


Figure 2. Percent of claim lines with food allergy diagnoses compared to all medical claim lines by state, 2016.

States with the highest percentage of food allergy diagnoses did not consistently remain at that level over time. The top five states for percent of claim lines with food allergy diagnoses in 2009 were (in order from highest to lowest) New York, Georgia, Colorado, North Dakota and Ohio. The top five states in 2016 were (in order from highest) North Carolina, North Dakota, New Jersey, Washington, DC, and Connecticut. North Dakota remained in the top five in both years, but all the other states changed. It is not known whether there are any environmental or genetic risk factors that would account for North Dakota’s persistent association with food allergy.

One area of consistency among the top five states for percent of claim lines with food allergy diagnoses in 2009 and 2016 was in the most common food allergies found in both years: egg, milk product, peanut and “other” (a category that includes all nuts other than peanut). Those four allergens accounted for the top three food allergy diagnoses in all the top five states in both years, except for one outlier: seafood in North Carolina in 2016 (tables 1 and 2).

Table 1. Most common food allergy diagnoses by state, 2009 (diagnoses for each state ranked in order from most common).

Rank	Colorado	Georgia	New York	North Dakota	Ohio
1	egg	other	milk product	other	milk product
2	other	egg	other	egg	Other
3	peanut	peanut	peanut	peanut	Peanut

Table 2. Most common food allergy diagnoses by state, 2016 (diagnoses for each state ranked in order from most common).

Rank	Connecticut	New Jersey	North Carolina	North Dakota	Washington, DC
1	other	other	other	other	other
2	peanut	peanut	peanut	peanut	peanut
3	milk product	milk product	seafood	milk product	egg

The percent of claim lines with anaphylactic food reaction diagnoses compared to all medical claim lines for a state also increased in some parts of the country between 2009 (figure 3) and 2016 (figure 4). The top five states with an anaphylactic food reaction in 2009 were (in order from highest) Massachusetts, New York, Rhode Island, Maryland and Colorado. Two of those states—New York and Colorado—were also in the top five for food allergy diagnoses, suggesting the relatedness of the two diagnoses: A state with many cases of food allergy could also be expected to have many cases of anaphylactic food reaction. But the other three states—Massachusetts, Rhode Island and Maryland—were not in the top five for food allergy diagnoses in 2009, implying that the relationship may be more complex. One explanation for this finding may be cases in which a patient is previously undiagnosed with food allergy at the time he or she has an anaphylactic food reaction. A 2005 study showed that in 24 percent of cases in which epinephrine (an emergency medication for anaphylaxis) was administered in Massachusetts schools during a two-year period, the individual receiving the drug had not been known to have a life-threatening allergy.¹⁸

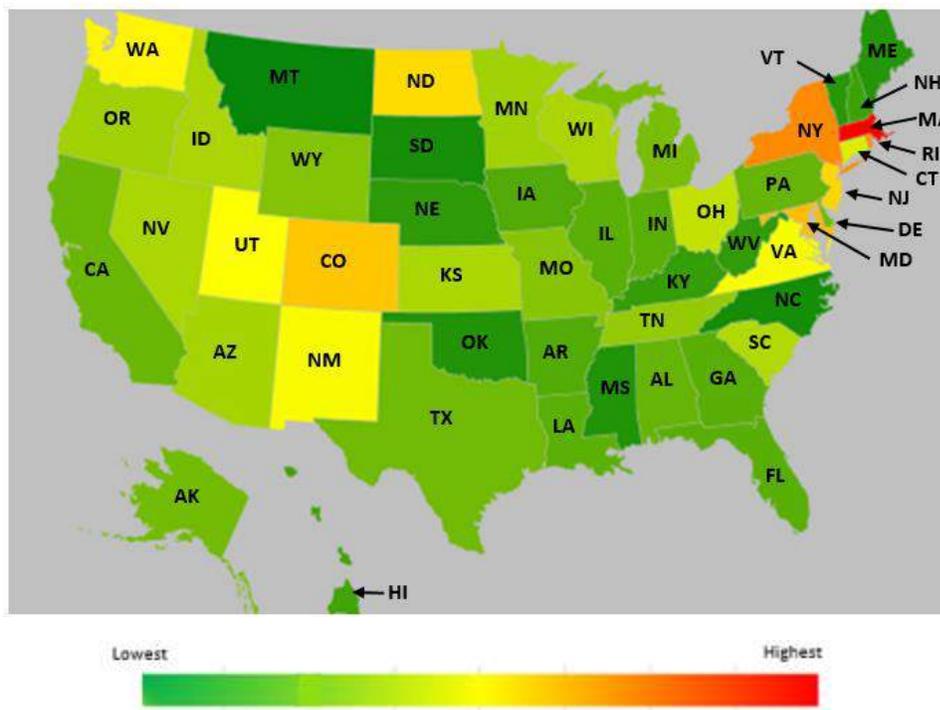


Figure 3. Percent of claim lines with anaphylactic food reaction diagnoses compared to all medical claim lines by state, 2009.

¹⁸ C. Lynne McIntyre et al., “Administration of Epinephrine for Life-Threatening Allergic Reactions in School Settings,” *Pediatrics* 116, no. 5 (2005): 1134-40.

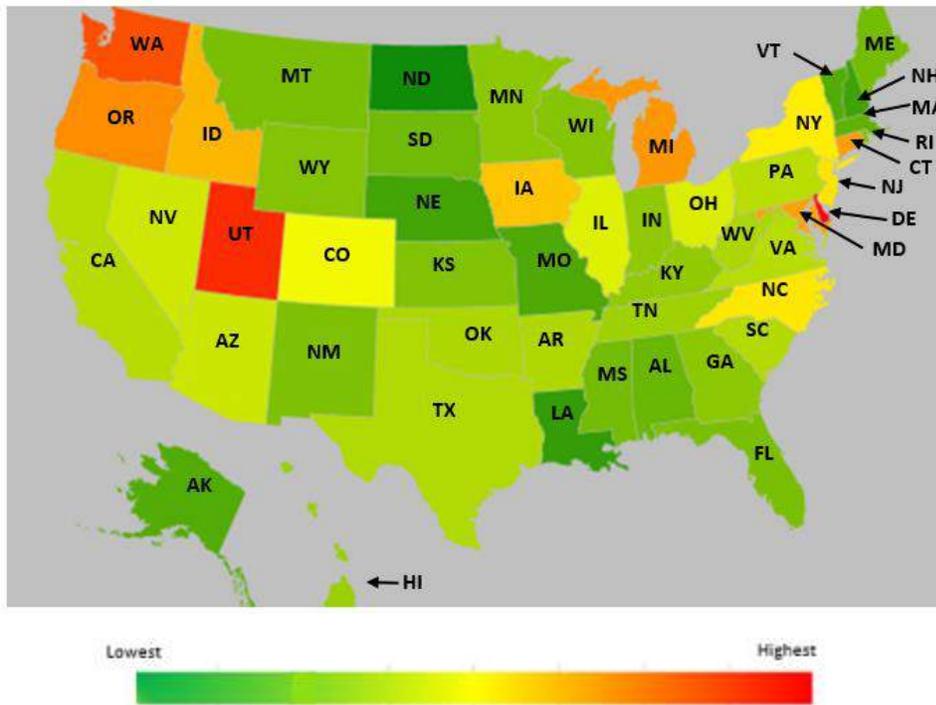


Figure 4. Percent of claim lines with anaphylactic food reaction diagnoses compared to all medical claim lines by state, 2016.

In 2016, the top five states for anaphylactic food reaction diagnoses were entirely different from the top five in 2009. The 2016 list was (in order from highest) Delaware, Utah, Oregon, Michigan and Connecticut. No states appeared on both the 2009 and 2016 top five anaphylactic food reaction lists. Connecticut was the only state in the top five for anaphylactic food reaction diagnoses in 2016 that was also in the top five for food allergy diagnoses that year.

As in the case of food allergy diagnoses, there was some consistency among the most common allergens identified in anaphylactic food reaction diagnoses in the top five states in 2009 and 2016 (tables 3 and 4). Both years showed a preponderance of peanut, tree nut/seed and “other,” particularly in 2016, when those were the only diagnoses in the top three for each state. (Tree nut/seed was included in “other” in the diagnosis codes for food allergy, but broken out as a separate diagnosis in the codes for anaphylactic food reaction.) In 2009, there was a little more diversity, with Colorado and Maryland both including egg, and Colorado including fruit and vegetable. None of the states’ top three lists included milk product or seafood, which were allergens identified for food allergy in the top five food allergy states in 2009/2016.

Table 3. Most common anaphylactic food reaction diagnoses by state, 2009 (diagnoses for each state ranked in order from most common).

Rank	Colorado	Maryland	Massachusetts	New York	Rhode Island
1	fruit/vegetable	other	other	other	other
2	other	egg	tree nut/seed	peanut	tree nut/seed
3	egg	peanut	peanut	tree nut/seed	peanut

Table 4. Most common anaphylactic food reaction diagnoses by state, 2016 (diagnoses for each state ranked in order from most common).

Rank	Connecticut	Delaware	Michigan	Oregon	Utah
1	other	peanut	peanut	peanut	peanut
2	peanut	tree nut/seed	other	tree nut/seed	tree nut/seed
3	tree nut/seed	other	tree nut/seed	other	other

Urban and Rural Patterns

A 2012 study found that the prevalence of childhood food allergy in the United States was greater in urban (9.8 percent) than rural (6.2 percent) areas.¹⁹ Findings from FAIR Health’s analysis reflect that distribution, showing that 60 percent of the distribution of claim lines with food allergy diagnoses in 2016 occurred in urban areas and 40 percent in rural areas (figure 5).

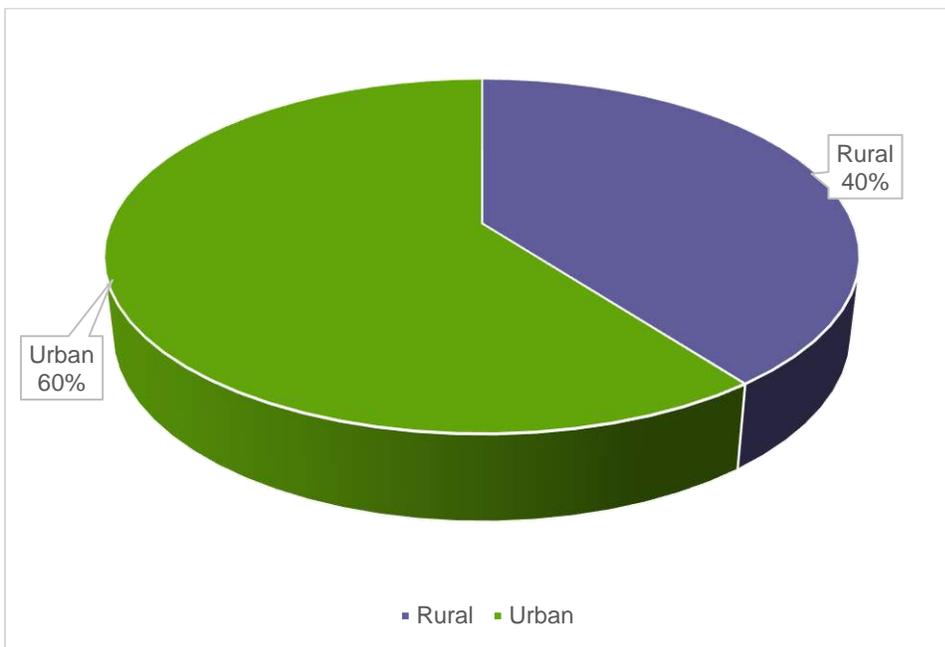


Figure 5. Urban/rural distribution of claim lines with food allergy diagnoses, 2016.

A similar distribution was found for claim lines with diagnoses of anaphylactic food reaction in 2016: 57 percent urban, 43 percent rural (figure 6).

¹⁹ Ruchi S. Gupta, “Geographic Variability of Childhood Food Allergy in the United States,” *Clin Pediatr (Phila)* 51, no. 9 (2012): 856-61; doi:10.1177/0009922812448526.

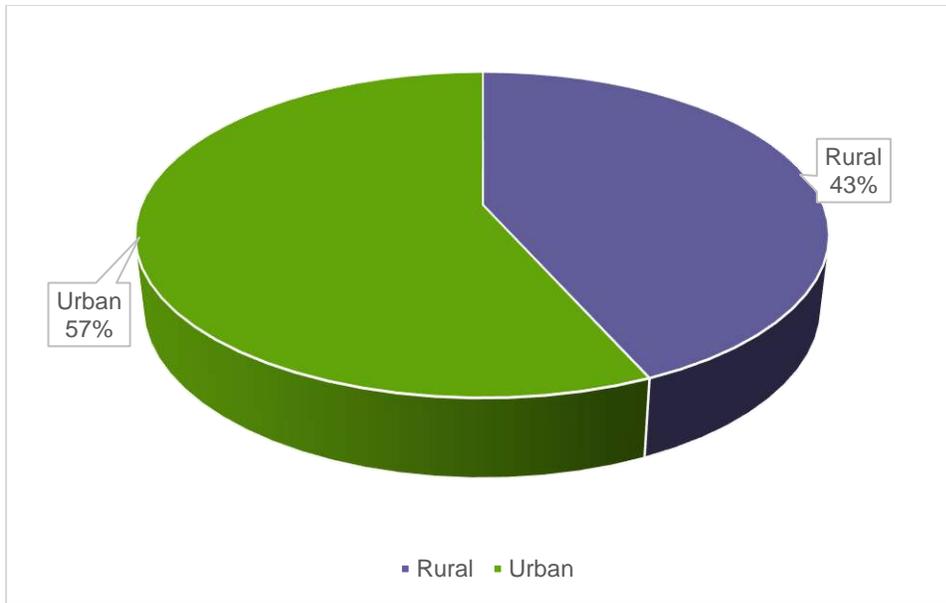


Figure 6. Urban/rural distribution of claim lines with anaphylactic food reaction diagnoses, 2016.

Despite the evidence of greater prevalence of food allergy in urban than rural areas, there were increases in food allergy diagnostic claims in rural as well as urban areas. From 2007 to 2016, claim lines with food allergy diagnoses increased in both rural and urban areas (although the percent of total claim lines associated with food allergy diagnoses in each area decreased in 2016), and the increase was greater in rural (110 percent) than urban (70 percent) settings (figure 7). The greater growth in rural than urban areas calls into question the “hygiene hypothesis,” which postulates a protective effect against allergy from farm living due to greater childhood exposure to microbes.²⁰

²⁰ Sally F. Bloomfield et al., “Too Clean, or Not Too Clean: The Hygiene Hypothesis and Home Hygiene,” *Clin Exp Allergy* 36, no. 4 (2006): 402-25.

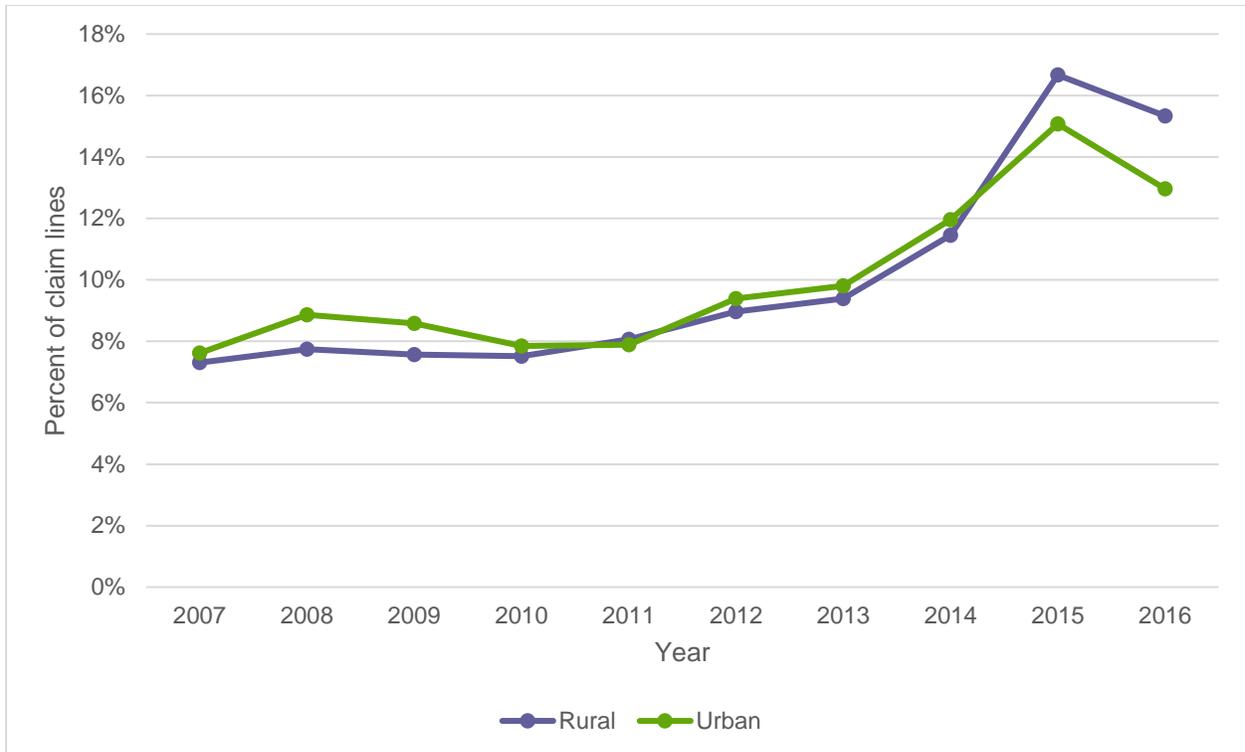


Figure 7. Claim lines with food allergy diagnoses in rural and urban settings, 2007-2016.

Anaphylactic Food Reactions

While the increase in claim lines with food allergy diagnoses from 2007 to 2016 was remarkable (110 percent in rural settings, 70 percent in urban settings), the increase in claim lines with diagnoses of anaphylactic food reactions during the same period was even more striking: 377 percent (figure 8). The disparity may seem puzzling, since an anaphylactic food reaction occurs as a result of a food allergy, so that it might seem the increase should be the same for both. As noted earlier, however, anaphylactic food reaction diagnoses can and do occur in the absence of prior food allergy diagnoses. Therefore, it is not surprising that claim lines for the two diagnoses present different trends.

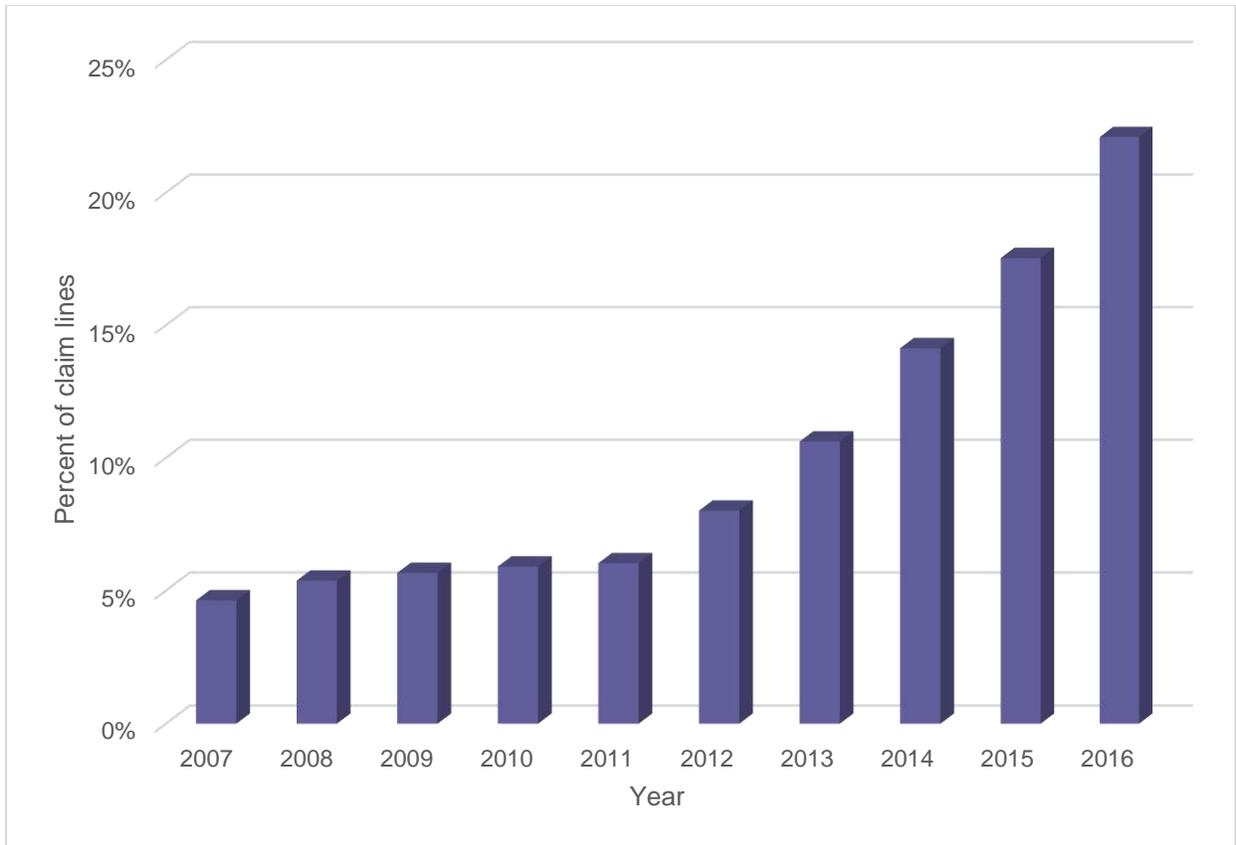


Figure 8. Claim lines with diagnoses of anaphylactic food reactions, 2007-2016.

The US Food & Drug Administration (FDA) identifies eight foods as the most common allergenic foods, accounting for 90 percent of food allergic reactions: crustacean shellfish, eggs, fish, milk, peanuts, soybeans, tree nuts and wheat.²¹ When FAIR Health analyzed the claim lines with diagnoses of anaphylactic food reaction during the period 2007-2016 by type of food, all of these, except for soybeans and wheat, appeared among the allergenic foods responsible for the reactions (figure 9). The reason for the absence of soybean- and wheat-induced anaphylaxis is that they do not have distinct diagnostic codes, but are categorized as “other specific foods.” Indeed, “other specific foods” was the most common group of food allergens (33 percent of claim lines), which includes not only foods that less commonly cause allergies but cases in which the actual food allergen is not known.

²¹ “Food Allergies: What You Need to Know,” US Food & Drug Administration, March 2017, <https://www.fda.gov/downloads/Food/ResourcesForYou/Consumers/UCM220117.pdf>.

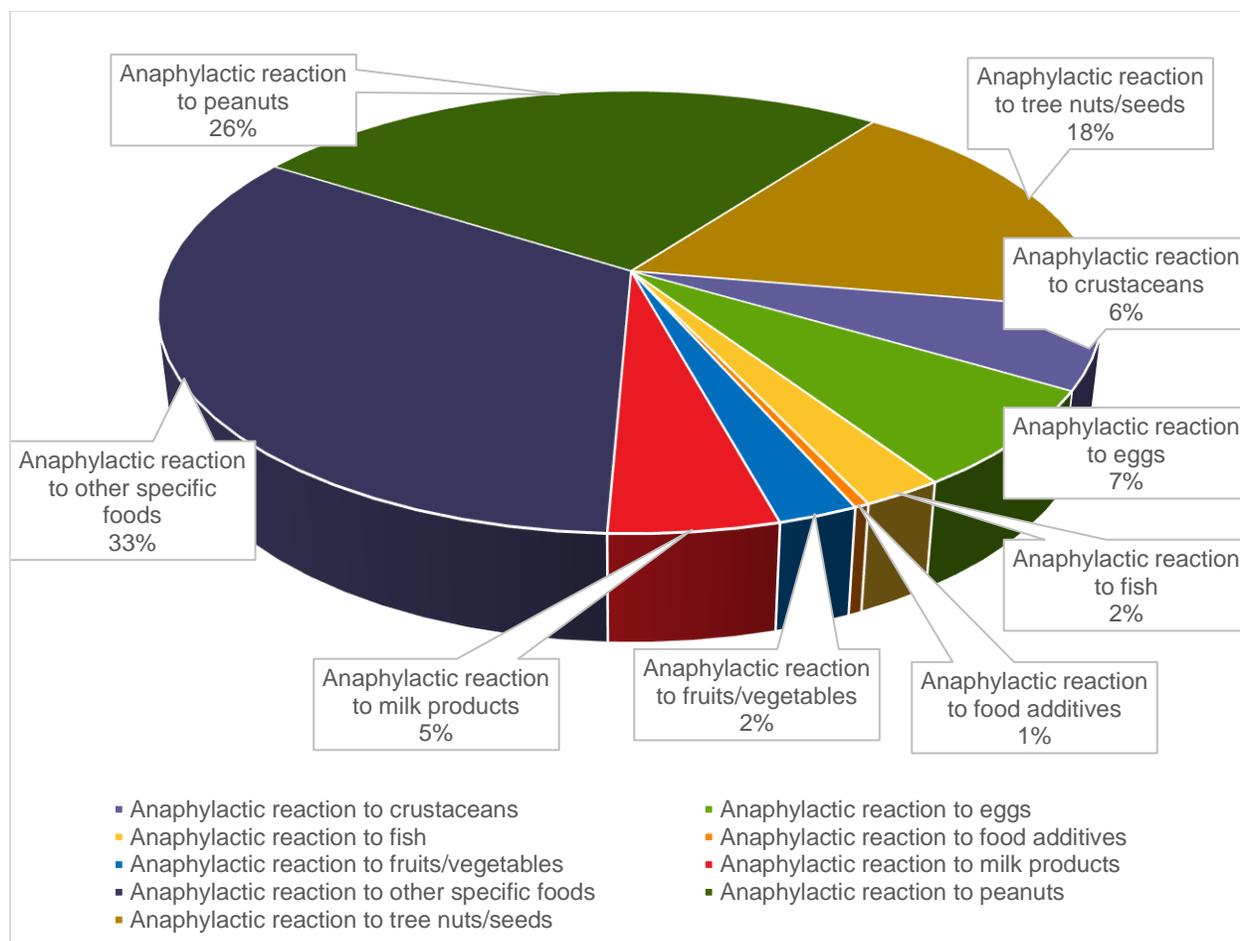


Figure 9. Claim lines with anaphylactic food reaction diagnoses by type of food, 2007-2016.

Among specifically identified foods causing anaphylaxis, the most common was peanut (26 percent), followed closely by tree nut/seed (18 percent). This finding is consistent with the finding described above (table 4), in which “other,” peanut and tree nut/seed were the top three anaphylactic food reaction diagnoses for all of the five states that had the greatest prevalence of anaphylactic food reaction diagnoses in 2016.

Egg allergy, crustacean allergy and milk product allergy were also common, making up, respectively, 7 percent, 6 percent and 5 percent of the anaphylactic food reaction claim lines. Fish and fruit/vegetable each accounted for 2 percent of the anaphylactic food reaction claim lines, and food additive for 1 percent. (Food additives may include a variety of ingredients, such as colors, emulsifiers, stabilizers, sweeteners and preservatives.²²)

In 2016, the incidence of billing with the “other specific foods” diagnosis code decreased, which was probably due to better training in the ICD-10-CM set of diagnostic codes and the great quantity of educational information about food allergies that had been disseminated over the years (figure 10). Claim lines associated with anaphylaxis due to “other specific foods” did not increase as much as anaphylactic food reactions attributed to a specific food or food category. “Other specific foods” had only a 71 percent

²² Mozghan Moghtaderi, “Sensitization to Food Additives in Patients with Allergy: A Study Based on Skin Test and Open Oral Challenge,” *Iran J Allergy Asthma Immunol* 15, no. 3 (2016): 198-203.

increase from 2007 to 2016. By comparison, claim lines with diagnoses of peanut anaphylactic reactions increased 445 percent and those with diagnoses of tree nut/seed anaphylactic reactions increased 603 percent.

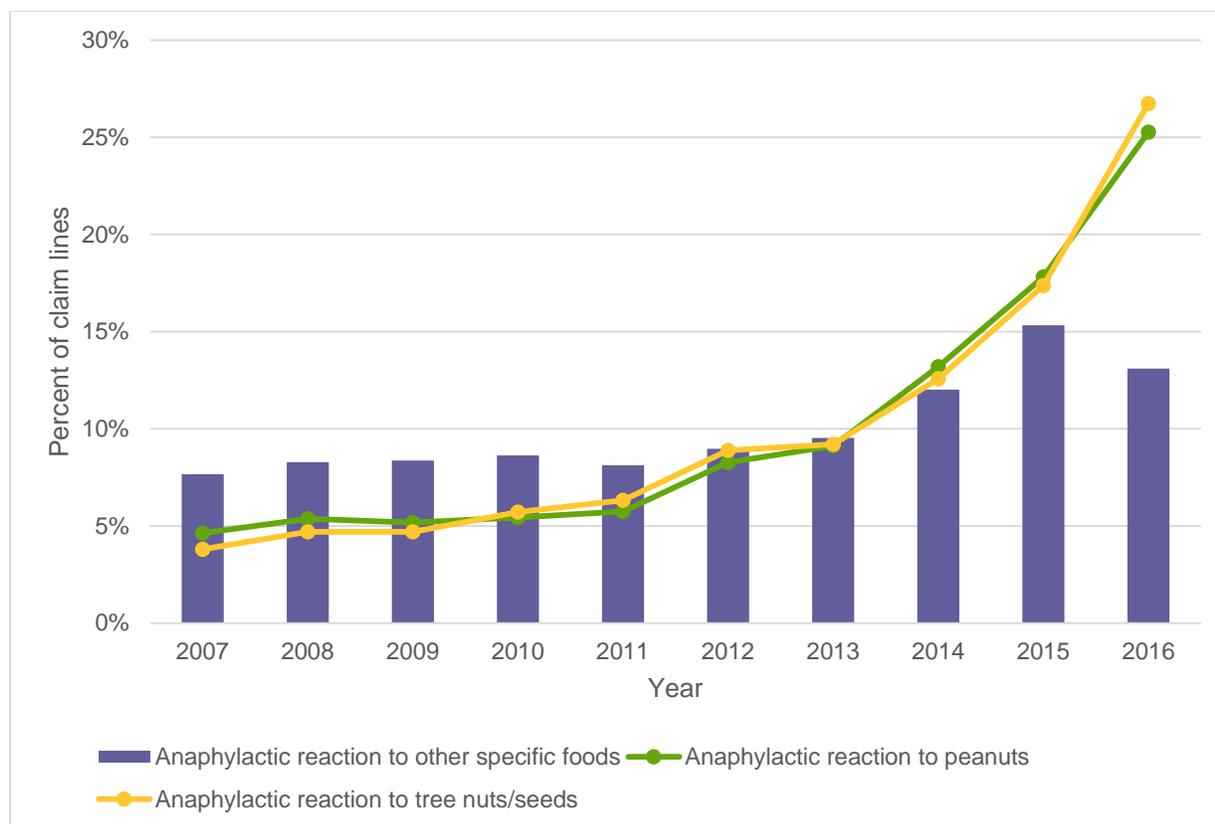


Figure 10. Claim lines with anaphylactic food reaction diagnoses attributed to peanuts, tree nuts/seeds and “other specific foods,” 2007-2016.

Demographic Patterns

Age

Although the majority of food allergy diagnoses occur in childhood, some of those allergies continue into adulthood, and food allergy can emerge for the first time in adults (adult-onset food allergy).²³ According to FAIR Health data, patients 18 years old and younger accounted for 66 percent of the claim lines with food allergy diagnoses in the period 2007-2016; those over 18 years old accounted for the remaining 34 percent (figure 11). Claim lines with food allergy diagnoses occurred in all age groups, even patients over 60 years old (4 percent).

²³ Shmuel Kivity, “Adult-Onset Food Allergy,” *Isr Med Assoc J* 14, no. 1 (2012): 70-72.

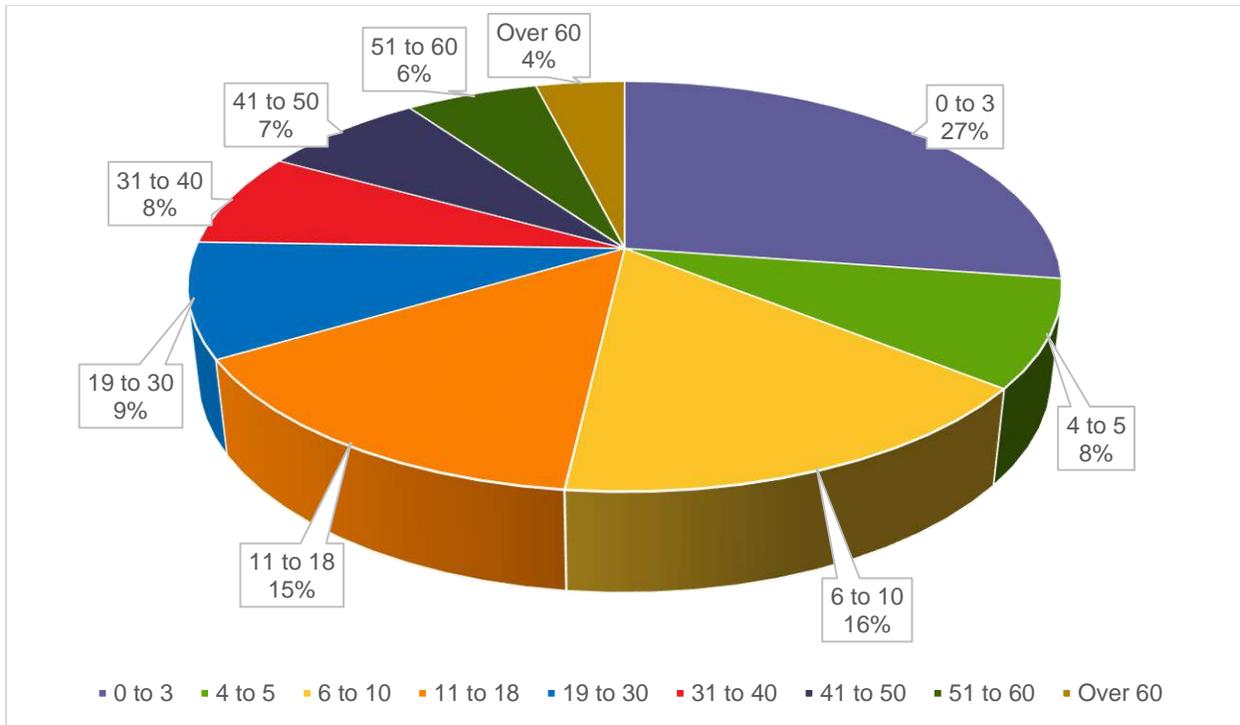


Figure 11. Claim lines with food allergy diagnoses by age group in years, 2007-2016.

Still, claims for children predominated. Almost a third (27 percent) of all claim lines with food allergy diagnoses were attributable to patients between the ages of 0 and 3. Preschool age children (4-to-5-year-olds) accounted for 8 percent of the total, with individuals ages 6 to 18 making up an additional third (31 percent).

The age distribution of claim lines with food allergy and anaphylactic reaction diagnoses in the period 2007-2016 varied by type of food. Peanut, for example, was responsible for claim lines with food allergy and anaphylaxis diagnoses primarily in people 18 years old and younger (figure 12). A high number of claims were seen in the age group 6 to 10 years, which accounted for 30 percent of all claim lines with anaphylactic reaction to peanut diagnoses and 28 percent of all claim lines with peanut allergy diagnoses.

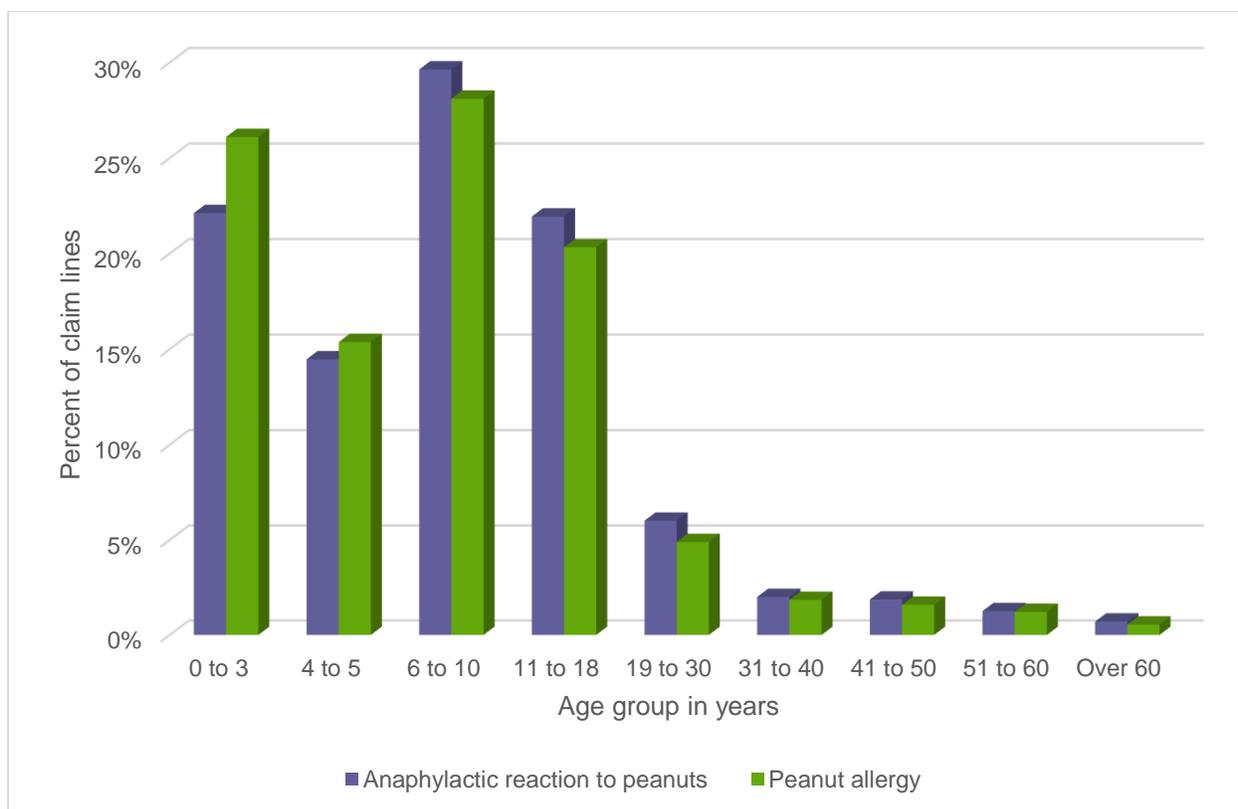


Figure 12. Claim lines with diagnoses of peanut allergy and anaphylactic reaction to peanuts by age group in years, 2007-2016.

It is notable that in the age groups from 6 to 30 years, claim lines with diagnoses of anaphylactic reaction to peanut were more common than claim lines with peanut allergy diagnoses, which was not the case in all other age groups. The years 6 to 30 are when children move into school settings with growing independence and young adults move away from their parents, and it may be that the diminution of parents' control over what their children eat leads to more cases of exposure to peanuts and anaphylactic reaction. More research will be needed to ascertain the precise cause of this difference.

Although the adult age groups had a much lower distribution of peanut-related diagnoses than the pediatric ones, it should not be concluded that the adults outgrew their peanut allergies. Although most children outgrow some food allergies, such as those to milk, egg, wheat and soy, in 80 to 90 percent of cases allergies to peanut, as also to tree nut, fish and shellfish, are lifelong allergies.²⁴ Peanut allergy most frequently emerges in childhood,²⁵ and it is likely that adults who have had a peanut allergy since childhood have learned to avoid exposure to peanuts and therefore avoid anaphylactic episodes and peanut allergy diagnoses.

The age distribution of claim lines with crustacean-related allergy and anaphylactic reaction diagnoses (figure 13) was very different from that of peanut-related diagnoses in the same period. ("Seafood allergy" is used in the figure because there is no specific diagnostic code for crustacean allergy; seafood includes crustaceans. There is, however, a specific diagnostic code for crustacean anaphylactic reaction.) Claim lines with anaphylactic reaction to crustacean and seafood allergy diagnoses began to climb in the age

²⁴ Nedeljko Radlović, "Food Allergy in Children," *Srp Arh Celok Lek* 144, nos. 1-2 (2016): 99-103.

²⁵ Kivity, "Adult-Onset Food Allergy."

group 6 to 10 years, and reached their peak among people aged 19 to 30 years, who had 18 percent of all claim lines with crustacean anaphylactic reaction and seafood allergy diagnoses. Unlike what was seen with peanut-related diagnoses, levels of crustacean-related diagnoses continued to be high in older adult groups. This may be because crustacean allergy is more commonly an adult-onset allergy than peanut allergy. One study found that the most common trigger food for adult-onset food allergy was shellfish.²⁶

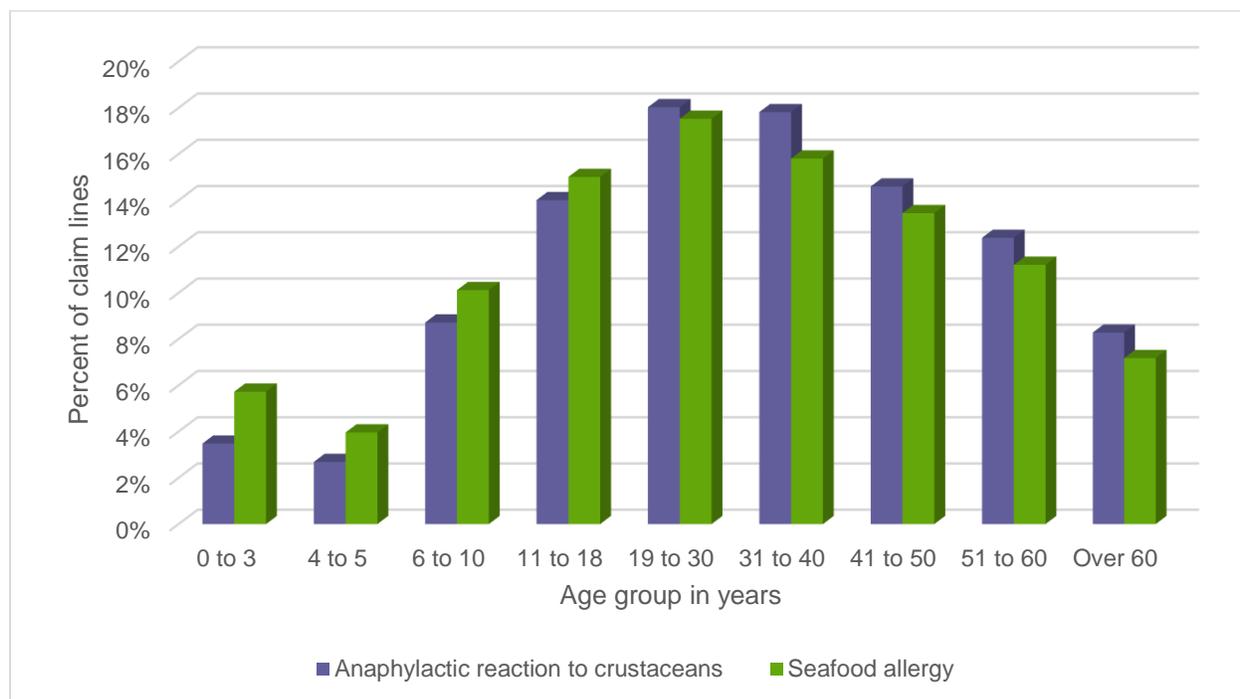


Figure 13. Claim lines with diagnoses of seafood allergy (including allergy to crustaceans) and anaphylactic reaction to crustaceans by age group in years, 2007-2016.

After the age of 18, the incidence of crustacean anaphylactic reaction diagnosis was greater than that of seafood allergy diagnosis, whereas among those 18 and younger the reverse was true. This could be related to the way the allergy manifests itself in adults, or to greater caution about the allergy in parents of young children who develop it.

Yet another type of age distribution was seen with allergy and anaphylactic reaction to food additives in the period 2007-2016 (figure 14). Claim lines with those diagnoses were spread much more evenly between children and adults than was the case with peanut- and crustacean-related diagnoses. The peak, however, was among the adults, in the age group 31 to 40 years, with 18 percent of all claim lines with anaphylactic reaction to food additive diagnoses and 13 percent of all food additive allergy diagnoses. In that age group, the percentage of anaphylactic reaction diagnosis claim lines was considerably higher than that of allergy diagnosis.

²⁶ Toral A. Kamdar, “Prevalence and Characteristics of Adult-Onset Food Allergy,” *J Allergy Clin Immunol Pract* 3, no. 1 (2015): 114–15.e1; doi:10.1016/j.jaip.2014.07.007.

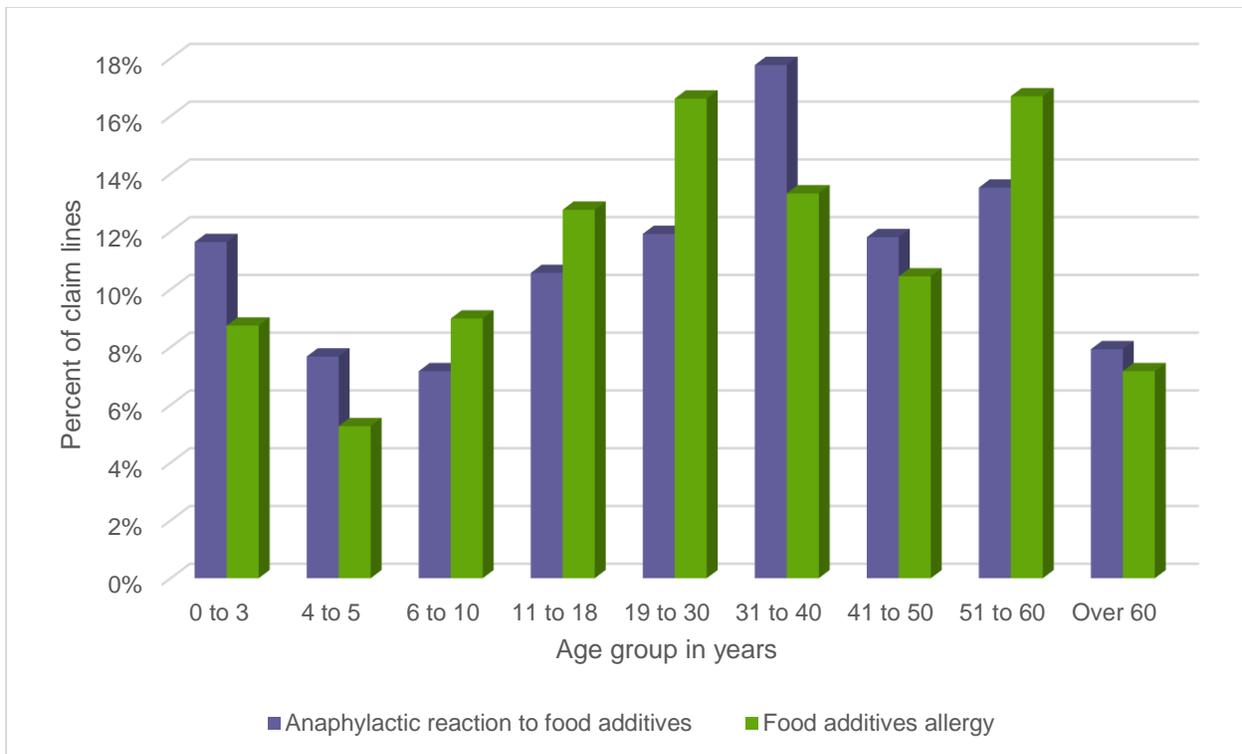


Figure 14. Claim lines with diagnoses of food additives allergy and anaphylactic reaction to food additives by age group in years, 2007-2016.

FAIR Health performed a longitudinal study of private insurance claims from a statistically significant cohort of individuals who had had a food allergy diagnosis from 2013 to 2016, to analyze by age group what percentage had an anaphylactic food reaction diagnosis later in that period (figure 15). The peak age group was children 4 to 5 years old, of whom 8 percent had an anaphylactic food reaction after being diagnosed with food allergy. Children 6 to 10 years old had the second highest percentage (7 percent) and 0- to 3-year-olds had the third highest (6 percent). Among adults, the percentages were much lower: Between 2 and 3 percent of adults from 19 years to over 60 years had an anaphylactic reaction to a food to which they were allergic. Possible reasons for these findings are that adults diagnosed with a food allergy may be better able to control their exposure to the food to which they are allergic, or perhaps that adults are less prone to anaphylactic food reaction if they do come in contact with an allergenic food.

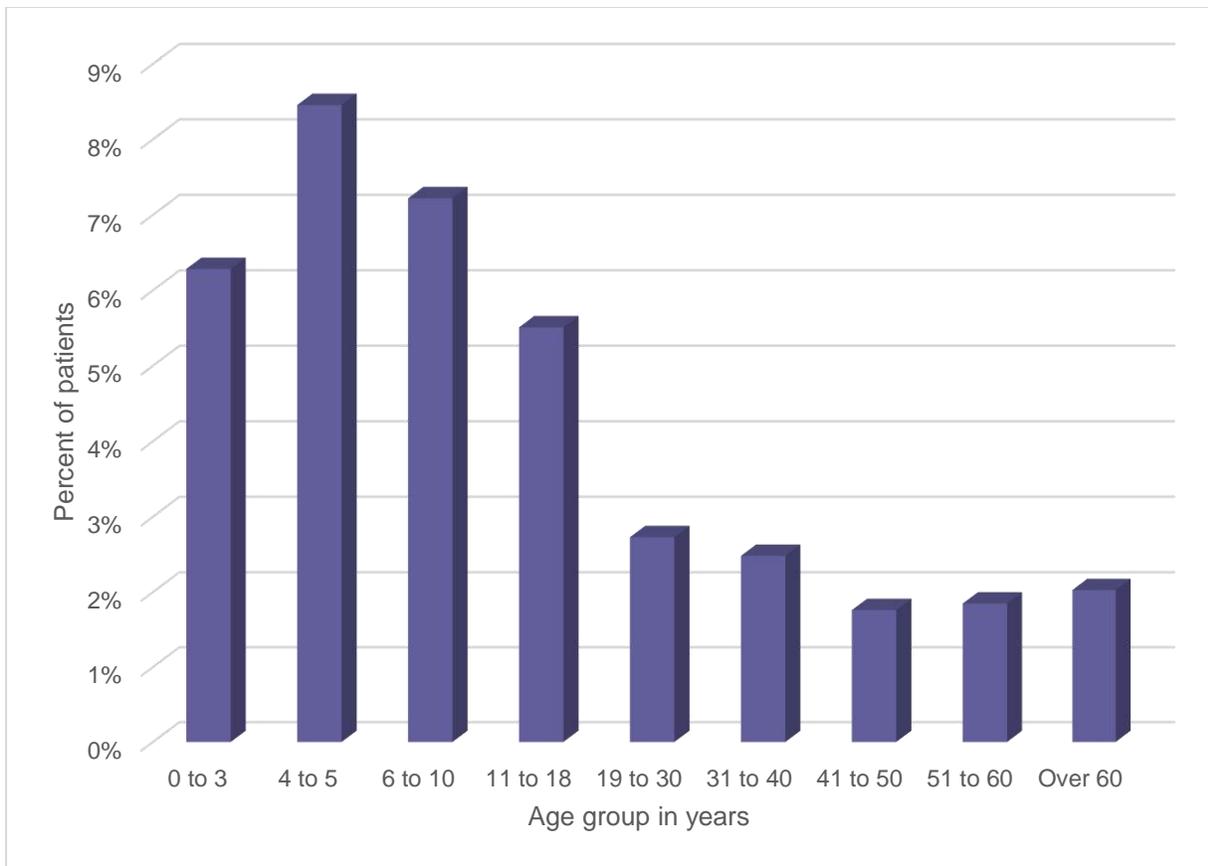


Figure 15. Percent of patients with a food allergy diagnosis who subsequently had an anaphylactic food reaction diagnosis, by age group in years, 2013-2016.

Gender

It has been reported that male gender is a risk factor for food allergy.²⁷ But FAIR Health evidence suggests that the risk may depend on the specific allergy and the age of the patient. Analyzing the gender distribution of claim lines with diagnoses of allergies to various foods from 2007 to 2016, FAIR Health found that more claim lines of male patients were associated with peanut, egg and milk product allergy diagnoses, but that more claim lines for women were related to seafood and food additive allergy diagnoses (table 5). There may be many reasons for this difference, but one point to note is that peanut, egg and milk product allergies typically develop in childhood, whereas seafood and food additive allergies are more associated with adult onset. Women in general have been found to be more likely than men to visit physicians²⁸ and make use of healthcare services,²⁹ so they may seek treatment for symptoms of

²⁷ Andrew H. Liu et al., “National Prevalence and Risk Factors for Food Allergy and Relationship to Asthma: Results from the National Health and Nutrition Examination Survey 2005-2006,” *J Allergy Clin Immunol* 126, no. 4 (2010): 798–806.e13; doi:10.1016/j.jaci.2010.07.026.

²⁸ Jill J. Ashman, Esther Hing and Anjali Talwalkar, “Variation in Physician Office Visit Rates by Patient Characteristics and State, 2012,” NCHS Data Brief, no. 212; Hyattsville, MD: National Center for Health Statistics, 2015; <https://www.cdc.gov/nchs/data/databriefs/db212.pdf>.

²⁹ Klea D. Bertakis et al., “Gender Differences in the Utilization of Health Care Services,” *J Fam Pract* 49, no. 2 (2000):147-52.

seafood and food additive allergies more than men with the same symptoms. Or, women may be more susceptible to these allergies—or both.

Table 5. Gender distribution of claim lines for specific food allergies, 2007-2016.

Allergy	Female	Male
Peanut	42%	58%
Egg	42%	58%
Milk product	45%	55%
Seafood	59%	41%
Food additive	66%	34%

An analysis of claim lines with food allergy diagnoses by age group and gender in the period 2007-2016 shows that such claim lines are associated with boys more than girls from birth through age 18, and that afterward the reverse is true: the preponderance of claim lines are associated with women rather than men (figure 16). As noted, this pattern could be due to greater healthcare-seeking behavior in women than men, or it could be that women have more adult-onset food allergies than men, or both. Further research into this pattern would be warranted. A 2009 systematic review of food allergy studies presented a similar finding: among children with food allergies, 64 percent were males; among adults with food allergies, 65 percent were females.³⁰

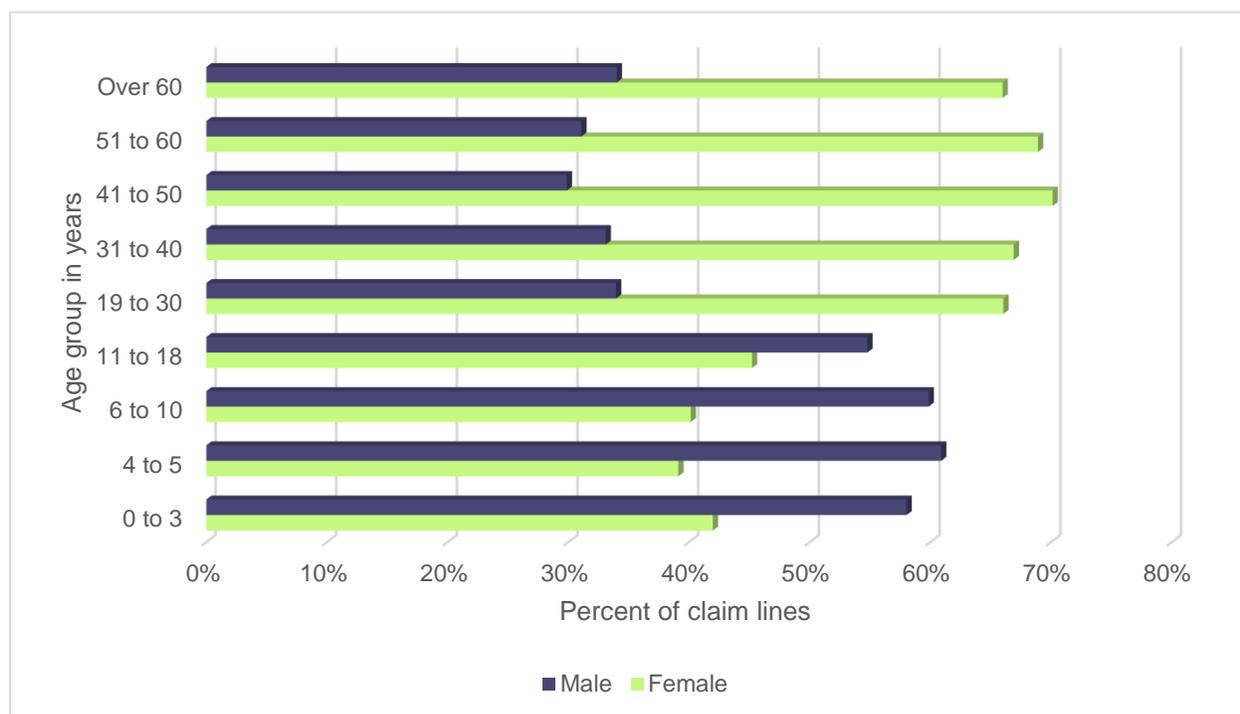


Figure 16. Claim lines with food allergy diagnoses by age group and gender, 2007-2016.

³⁰ Caleb Kelly and Venu Gangur, “Sex Disparity in Food Allergy: Evidence from the PubMed Database,” *J Allergy (Cairo)*, 2009:159845 (2009); doi:10.1155/2009/159845.

The age group and gender pattern found with food allergy in general is also found on the level of one of the most common specific allergies: peanut allergy. In the period 2007-2016, claim lines with diagnoses of peanut allergy (figure 17) and anaphylactic reaction to peanut (figure 18) were associated with boys more than girls up through the age of 18, and with women more than men after that age.

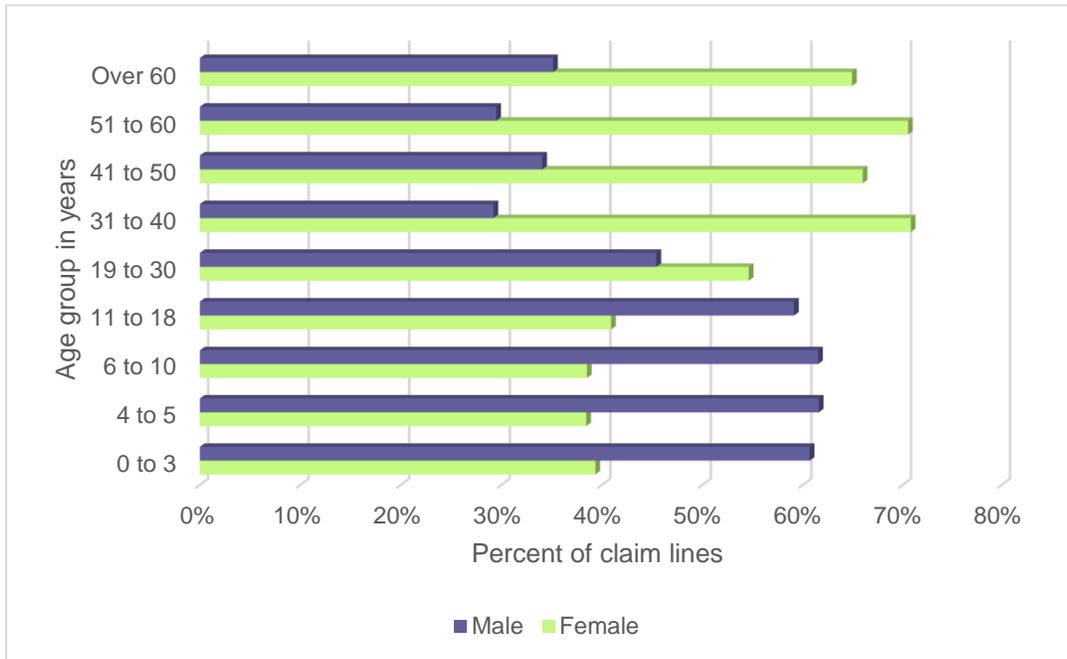


Figure 17. Claim lines with peanut allergy diagnoses by age group and gender, 2007-2016.

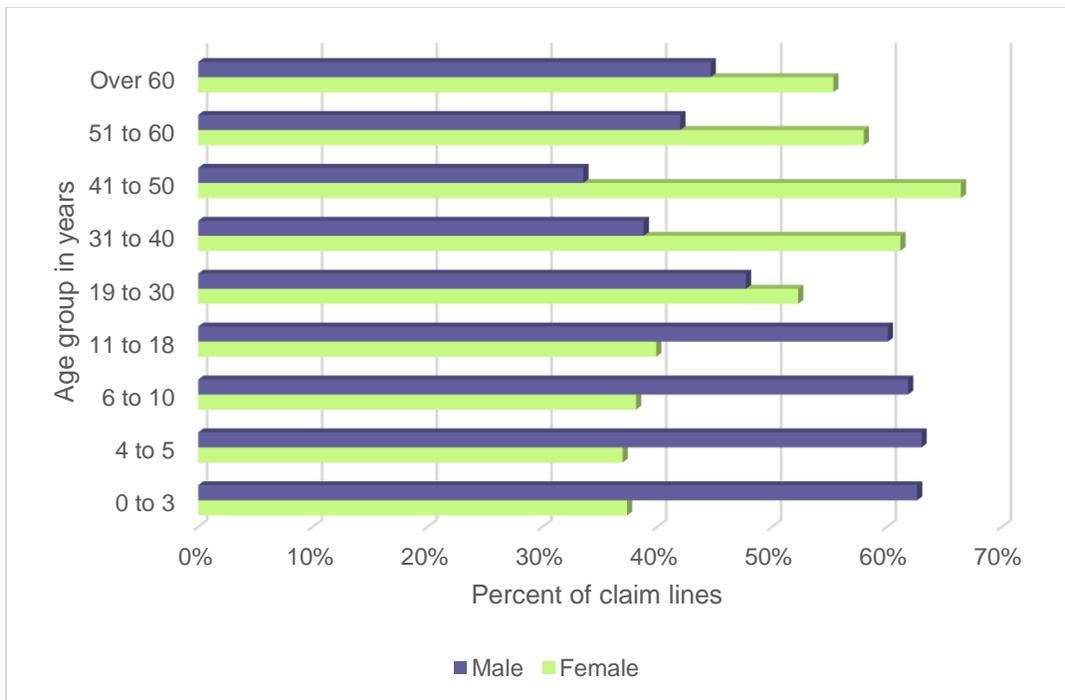


Figure 18. Claim lines with diagnoses of anaphylactic reaction to peanut by age group and gender, 2007-2016.

Place of Service for Anaphylactic Food Reactions

An anaphylactic food reaction is typically considered a medical emergency.³¹ Nevertheless, FAIR Health data show that the vast majority of claim lines with diagnoses of anaphylactic food reaction are associated with an office setting rather than an emergency room. In an analysis of claim lines with a diagnosis of anaphylactic food reaction in the period 2007-2016, 70 percent of claim lines were associated with an office as place of service, and only 2 percent specifically with an emergency room (figure 19). The second most common place of service was the outpatient facility setting (13 percent), which can include emergency rooms. The inpatient setting accounted for 9 percent of claim lines, laboratory 3 percent and all others 3 percent.

³¹ Centers for Disease Control and Prevention, “Voluntary Guidelines for Managing Food Allergies In Schools and Early Care and Education Programs”; Washington, DC: US Department of Health and Human Services, 2013; https://www.cdc.gov/healthyschools/foodallergies/pdf/13_243135_A_Food_Allergy_Web_508.pdf.

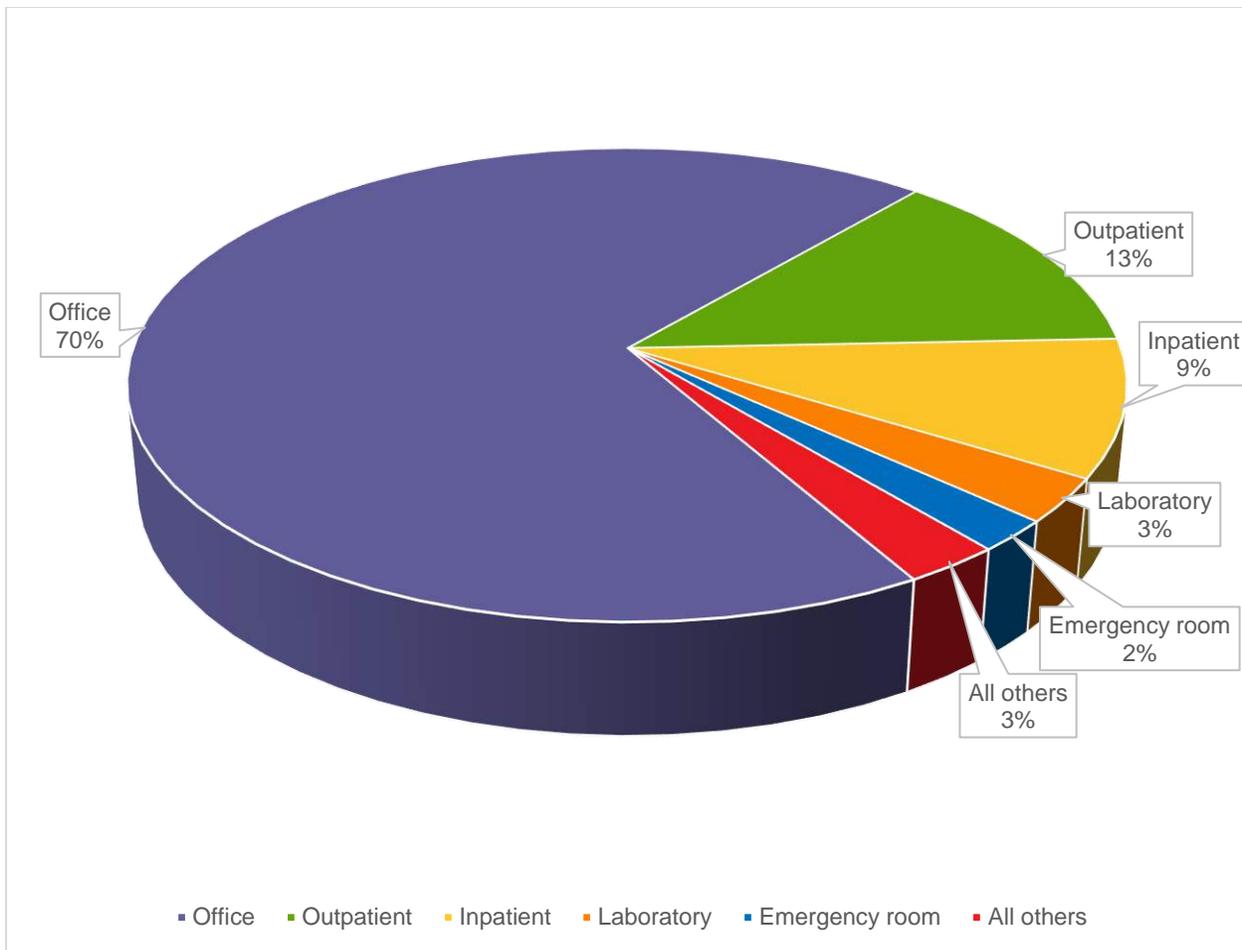


Figure 19. Distribution of claim lines with diagnoses of anaphylactic food reaction showing utilization of places of service, 2007-2016.

Although the office was the most common place of service associated with claim lines with an anaphylactic food reaction, it increased relatively little from 2007 to 2016, growing 216 percent (figure 20). Emergency room utilization also grew relatively little in that period, at 161 percent. The place of service with the highest growth was the outpatient facility setting, with an increase of 1,070 percent. Laboratory had the next highest increase, at 871 percent. Inpatient utilization grew at 229 percent.

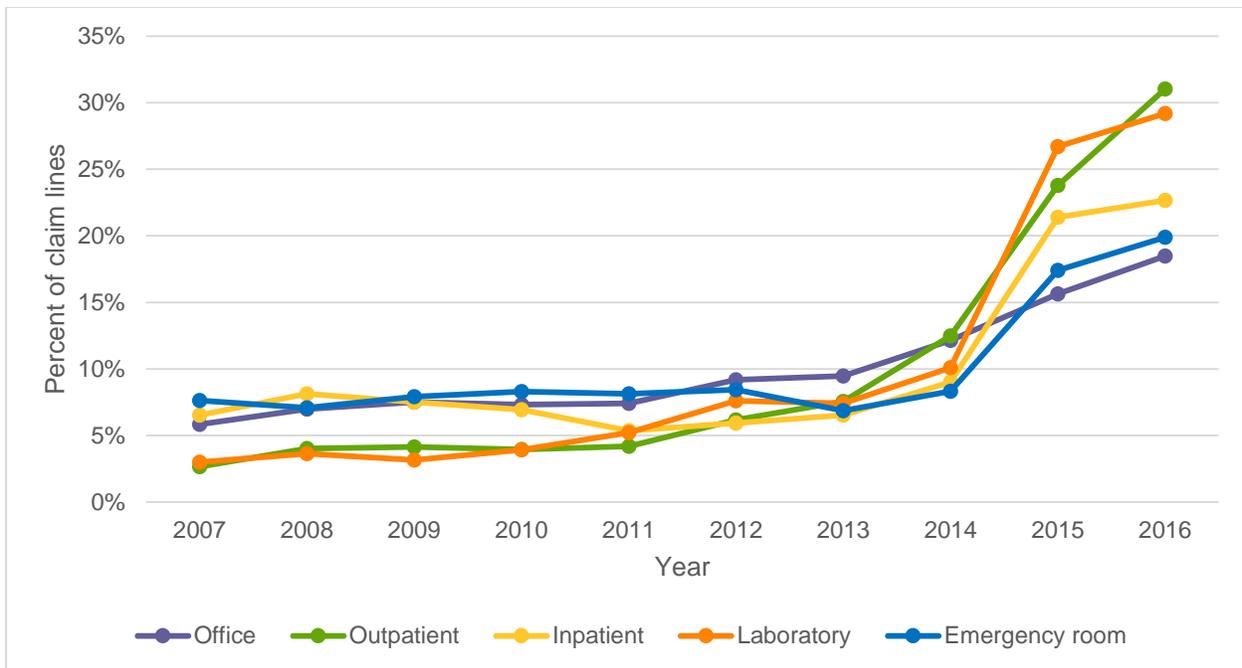


Figure 20. Trends in utilization of services associated with anaphylactic food reaction diagnoses, by place of service, 2007-2016.

The 2007-2016 distribution of providers' billed charges associated with anaphylactic food reaction claim lines (figure 21) was very different from the distribution of places of service by utilization in the same period (figure 19). Whereas 70 percent of such claim lines were associated with an office as place of service, only 51 percent of the charges were associated with the office setting, suggesting that the office was not as costly as the other places of service. Those other places of services, which made up 30 percent by utilization, accounted for 49 percent of charges. Specifically, outpatient facility, inpatient, laboratory and emergency room visits, which, respectively, comprised 13 percent, 9 percent, 3 percent and 2 percent of total services by utilization, accounted for, respectively, 17 percent, 13 percent, 8 percent and 7 percent of the total charges.

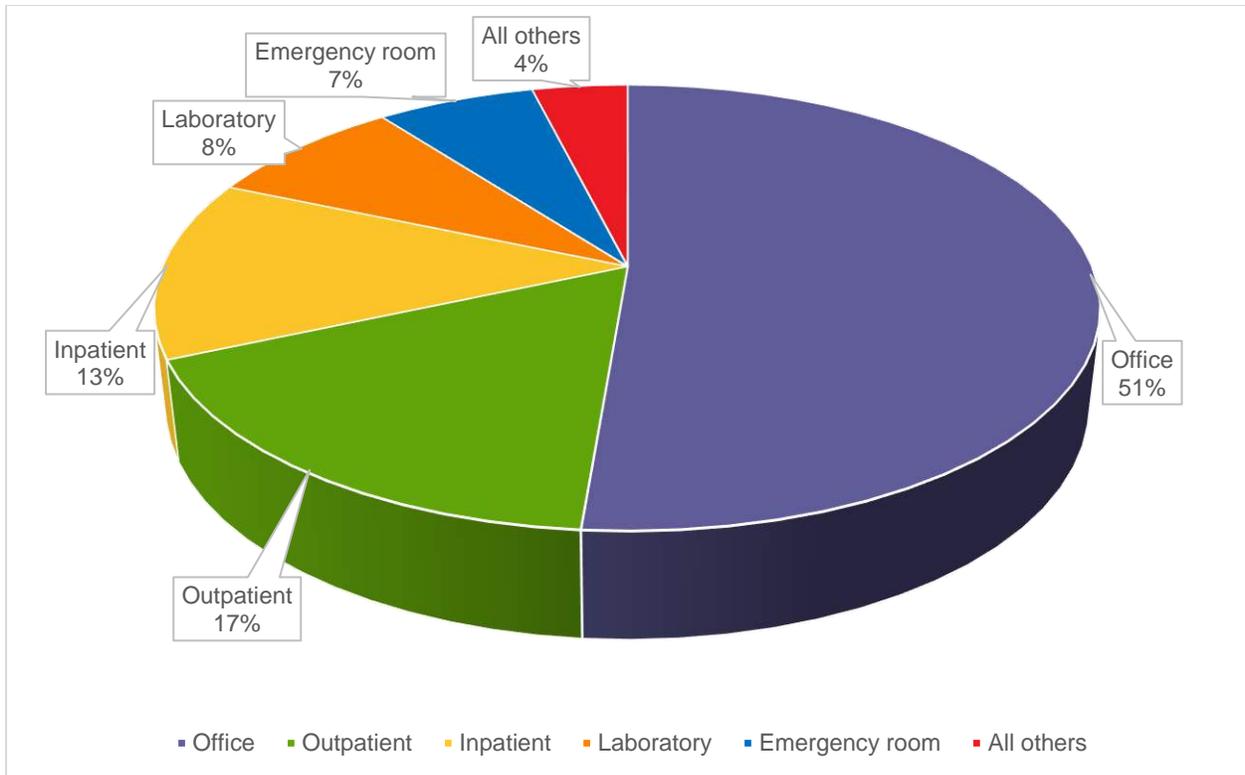


Figure 21. Distribution of charges associated with places of service for claim lines with anaphylactic food reaction diagnoses, 2007-2016.

The greatest increase in charges for services associated with diagnoses of anaphylactic food reaction from 2007 to 2016 occurred in the laboratory setting (figure 22). Though laboratory services increased in utilization 871 percent during that period, charges for those services increased 5,390 percent. The next greatest increase in charges was for emergency room services, which grew by 1,387 percent, even though utilization of emergency room services grew by only 161 percent.

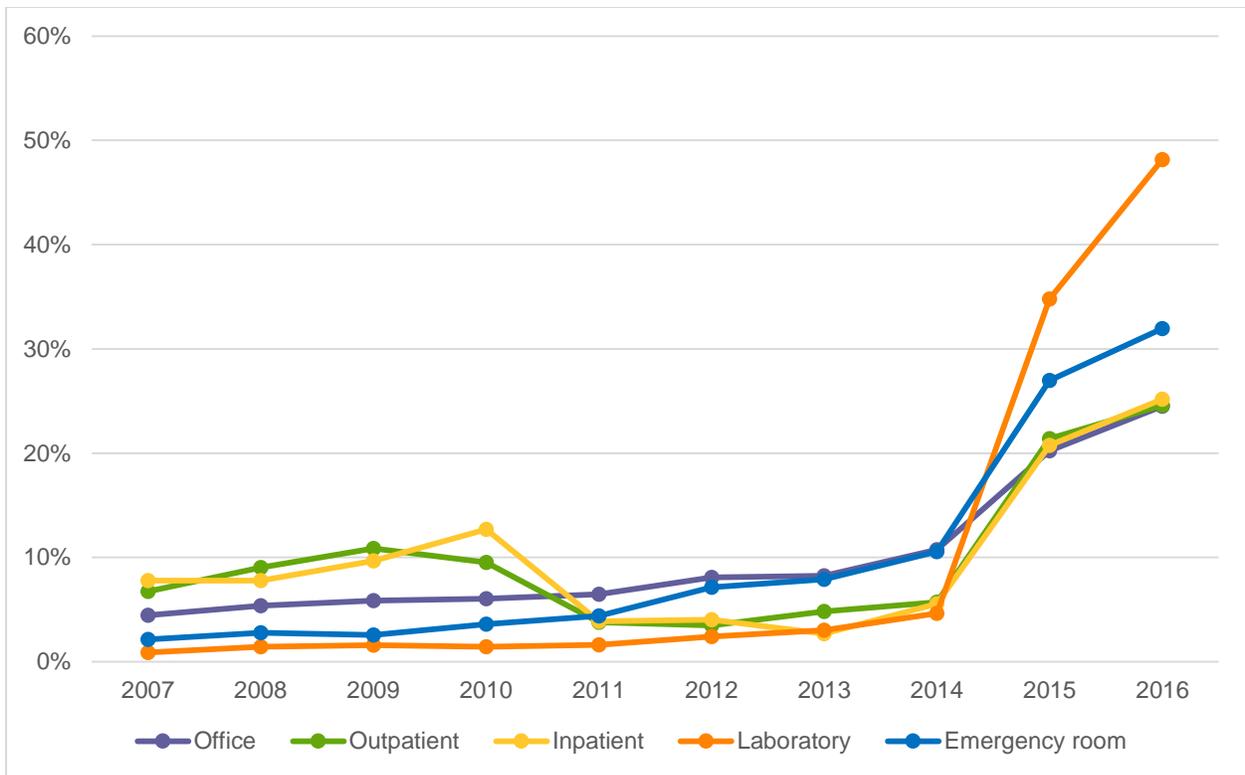


Figure 22. Trends in charges for services associated with anaphylactic food reaction diagnoses by place of service, 2007-2016.

Procedure Code Categories

The most common procedure code category associated with food allergy diagnoses in the period 2007-2016 was office or outpatient services to an established patient, which made up 21 percent of procedures (figure 23)—for example, CPT code 99213, office outpatient visit—15 minutes.

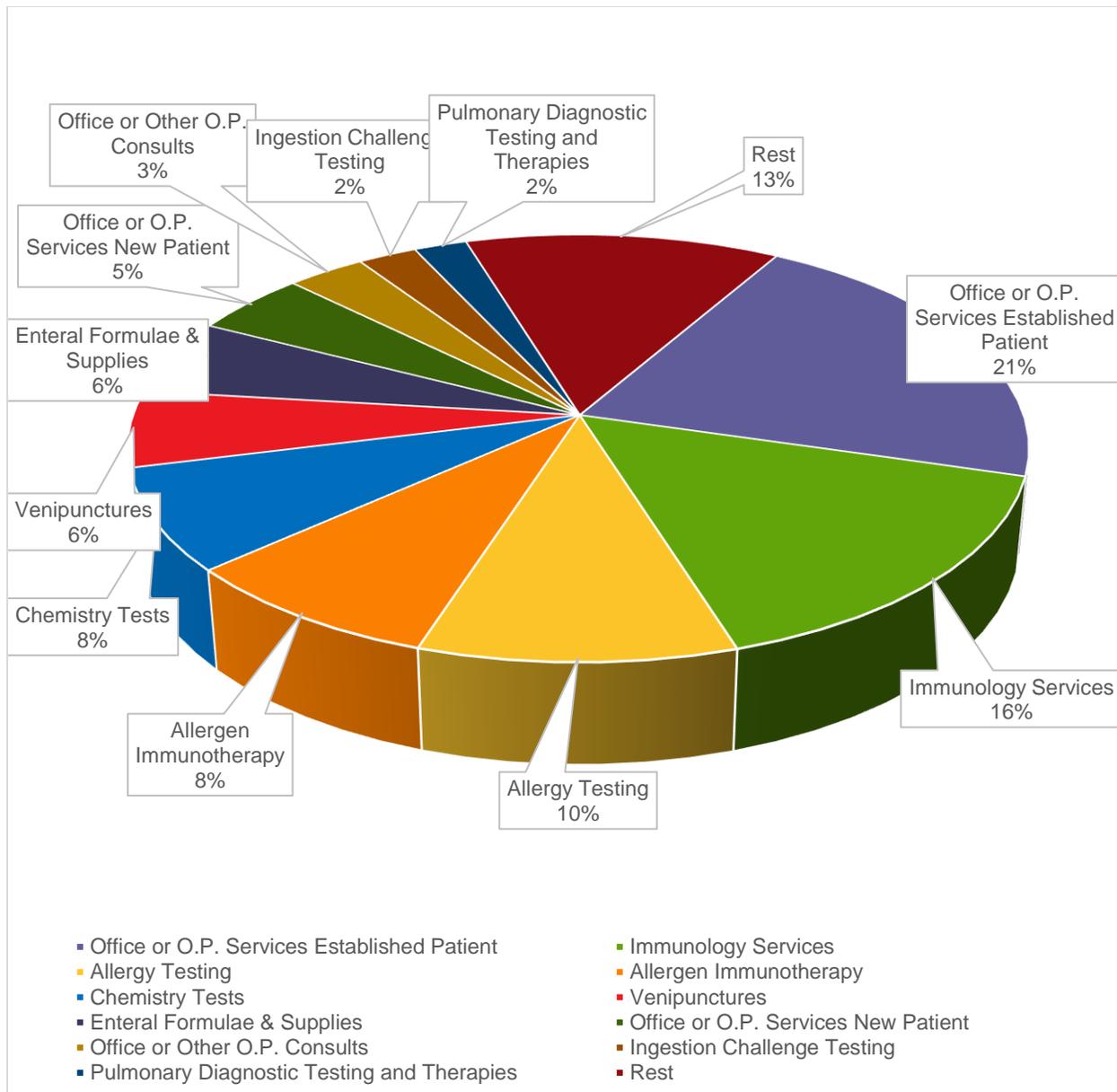


Figure 23. Most common procedure code categories associated with food allergy diagnoses, 2007-2016. “O.P.” is “outpatient.”

Immunology services were the second most common procedure code category (16 percent). An example was a laboratory test to identify specific allergens, CPT 86003, allergen specific IgE. Allergy testing was the third most common (10 percent). An example was CPT 95004, percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report. Allergen immunotherapy and chemistry testing, each 8 percent, were the fourth and fifth most common categories. An example of allergen immunotherapy was CPT 95117, professional services for allergy immunotherapy not including provision of allergenic extracts (i.e., allergy shots). An example of a chemistry test was CPT 82785, gammaglobulin (immunoglobulin); IgE.

Although not in the top five procedure code categories associated with food allergy diagnoses, enteral formulae and supplies were notable for making up 6 percent of all procedures. This category included substitutes for milk for children allergic to milk products. It included HCPCS codes such as B4161 (enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins; includes fats, carbohydrates, vitamins and minerals; may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit) and B4158 (enteral formula, for pediatrics, nutritionally complete with intact nutrients; includes proteins, fats, carbohydrates, vitamins and minerals; may include fiber and/or iron; administered through an enteral feeding tube, 100 calories = 1 unit). Although typically used when providing nutrition through a feeding tube, these enteral formulas also can be used for orally provided formulas that are prescription based.

Just as in the case of food allergy, the most common procedure code category associated with diagnoses of anaphylactic food reaction in the period 2007-2016 was office or outpatient services to an established patient, which made up 20 percent of procedures (figure 24). This could be a follow-up visit with a physician after an anaphylactic food reaction, or it could be a visit in which anaphylactic food reaction was diagnosed, and the patient could potentially be redirected to the emergency room.

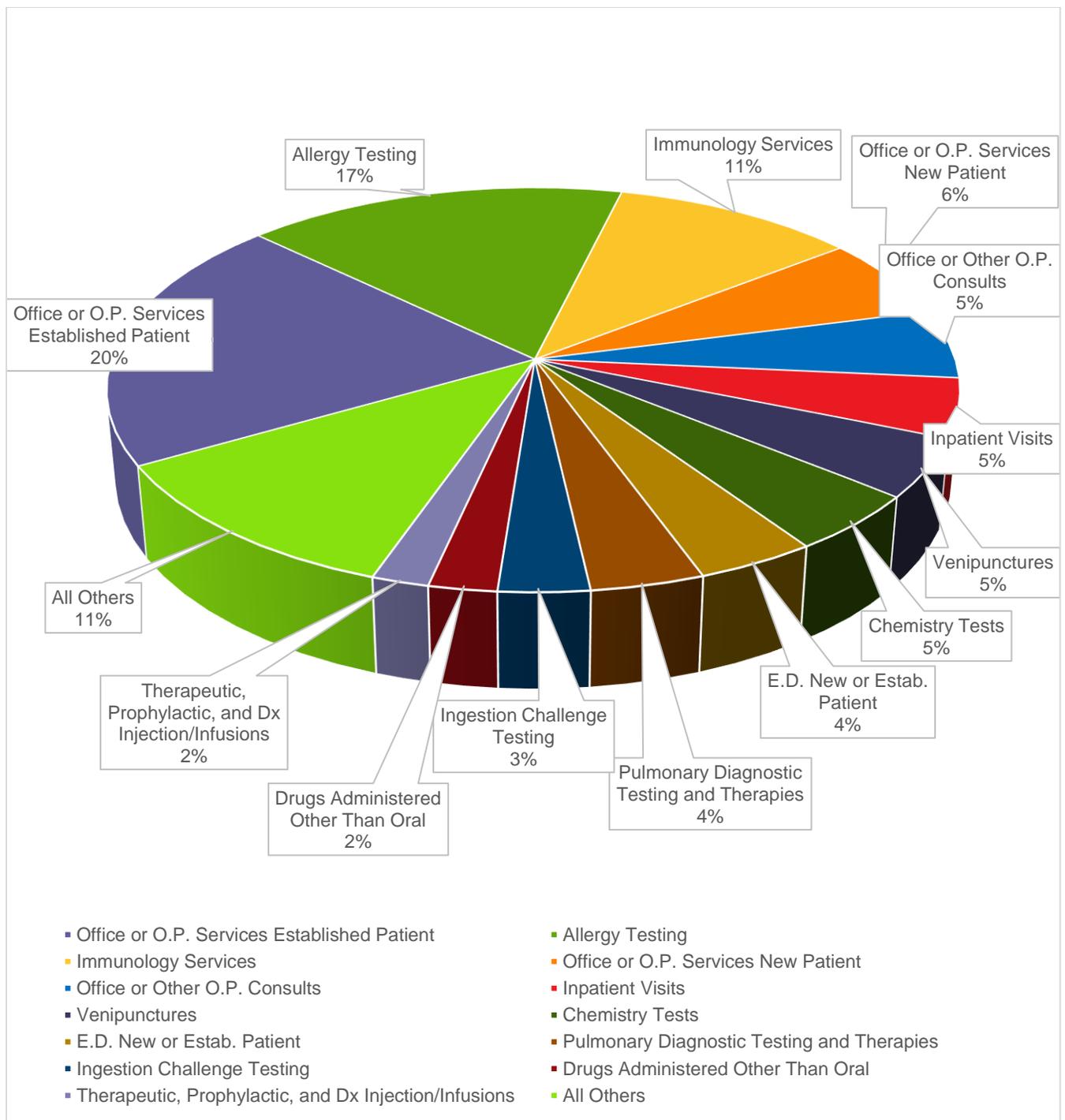


Figure 24. Most common procedure code categories associated with anaphylactic food reaction diagnoses, 2007-2016. “O.P.” is “outpatient”; “E.D.” is “emergency department” or “emergency room”; “Dx” is “diagnostic.”

Immunology services and allergy testing—respectively, the second and third most common procedure code categories associated with food allergy diagnoses—were very common with diagnoses of anaphylactic food reactions, but in reverse order: allergy testing was second (17 percent), immunology

services third (11 percent). In the context of anaphylactic food reactions, allergy testing and immunology services are typically performed to assess what the patient reacted to and to see if there are any additional foods or substances to which the patient may be severely allergic.

Although not among the most common procedure code categories associated with food allergy diagnoses, codes for new or established patients in the emergency room were common (4 percent) with diagnoses of anaphylactic food reaction, because of the emergency nature of that diagnosis.

Costs and Services per Patient

Food allergy has a substantial economic impact on the healthcare system, but its dimensions have been hard to measure. One 2013 study calculated direct annual medical costs of childhood food allergy as \$4.3 billion nationally, or \$724 per child with food allergy, based on a survey of parents with children who had food allergies and standard measures of costs for different services, such as outpatient visits and emergency room visits.³² By analyzing claims associated with food allergy diagnoses, FAIR Health was able to get more precise estimates of the average number of services and the average costs per patient in a single year, 2016 (figure 25). Costs included both the charges that providers billed for their services and the allowed amounts, the maximum amount an insurer will pay for a covered health service. The allowed amounts were imputed by FAIR Health based on its data on allowed amounts. Patients included both children and adults, and the results were broken down by type of allergy.

³² Ruchi Gupta et al., “The Economic Impact of Childhood Food Allergy in the United States,” *JAMA Pediatr* 167, no. 11 (2013): 1026-1031; doi:10.1001/jamapediatrics.2013.2376.

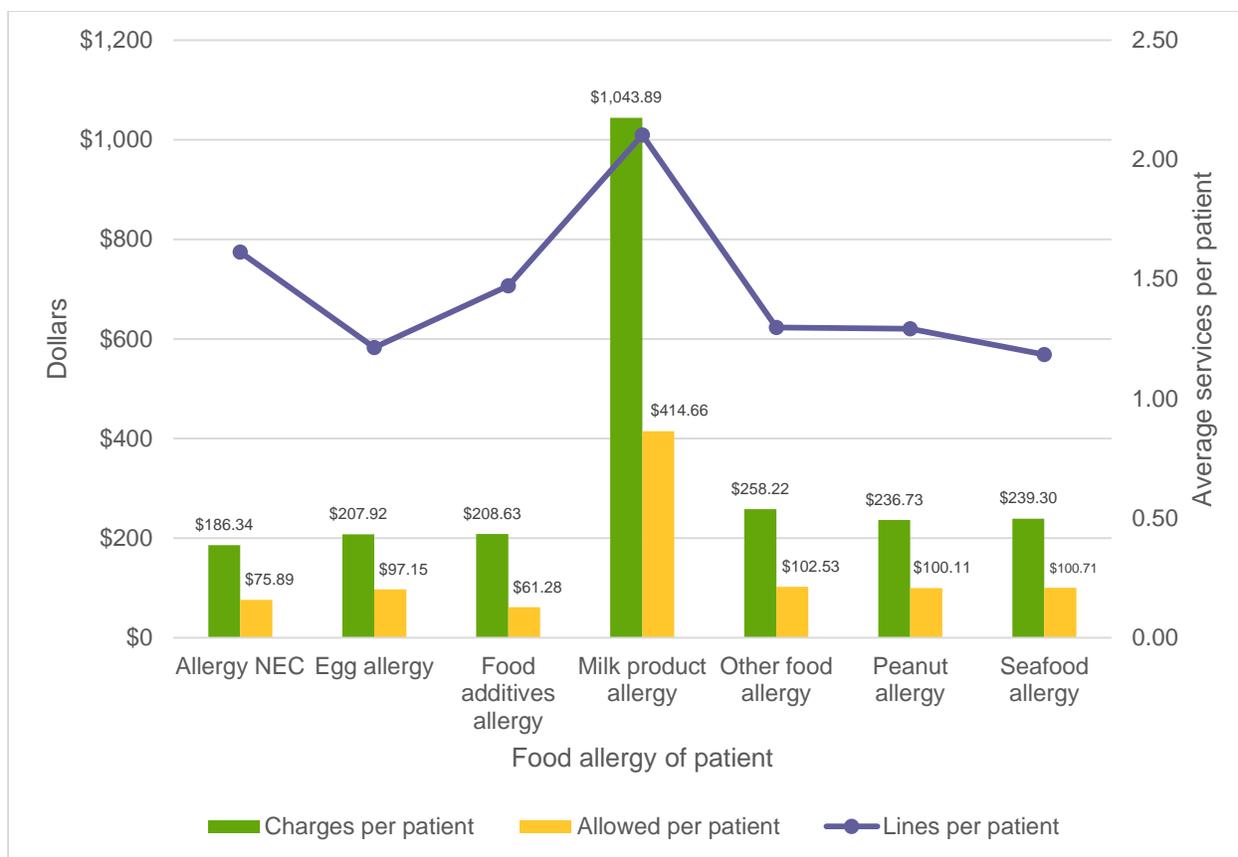


Figure 25. Average annual costs and services per patient diagnosed with food allergy, by type of allergy, 2016. “Lines” are “services.” “NEC” is “not elsewhere classified.”

The average number of services per patient varied from 1.18 for seafood allergy to 2.10 for milk product allergy. There was similar variation in average charges and allowed amounts: Average charges varied from a low of \$186.34 for allergy not elsewhere classified to a high of \$1,043.89 for milk product allergy; average allowed amounts varied from a low of \$61.28 for food additives allergy to a high of \$414.66 for milk product allergy. Milk product allergy stood out consistently for greatest average number of services and greatest average costs. This is likely because milk product allergy is associated with the youngest population, infants and toddlers, and poses risks to their nutrition and growth.³³ This allergy tends to be associated with prescription-based formulas, as described in relation to figure 23.

Average services and costs per patient diagnosed with anaphylactic food reaction in 2016 (figure 26) presented a somewhat different picture from that associated with food allergy diagnoses (figure 25). With anaphylactic food reaction there was less variation in average number of services (1.25 to 1.39), charges (\$276.31 to \$820.52) and allowed amounts (\$145.49 to \$272.27). The highest average number of services was for anaphylactic reaction to milk product, but the highest average costs (both charges and allowed amounts) were for anaphylactic reaction to fish. This may be in part because anaphylactic reaction to fish is relatively uncommon, accounting for just 2 percent of the claim lines with anaphylactic food reaction diagnoses in the period 2007-2016 (figure 9). In addition, fish products may be found in

³³ Karen A. Robbins, Robert A. Wood and Corinne A. Keet, “Milk Allergy Is Associated with Decreased Growth in U.S. Children,” *J Allergy Clin Immunol* 134, no. 6 (2014): 1466–1468.e6; doi:10.1016/j.jaci.2014.08.037.

unexpected places, such as barbecue sauce, Caesar salad and Worcestershire sauce,³⁴ and there may have to be extensive testing until the trigger for the anaphylactic reaction is found.

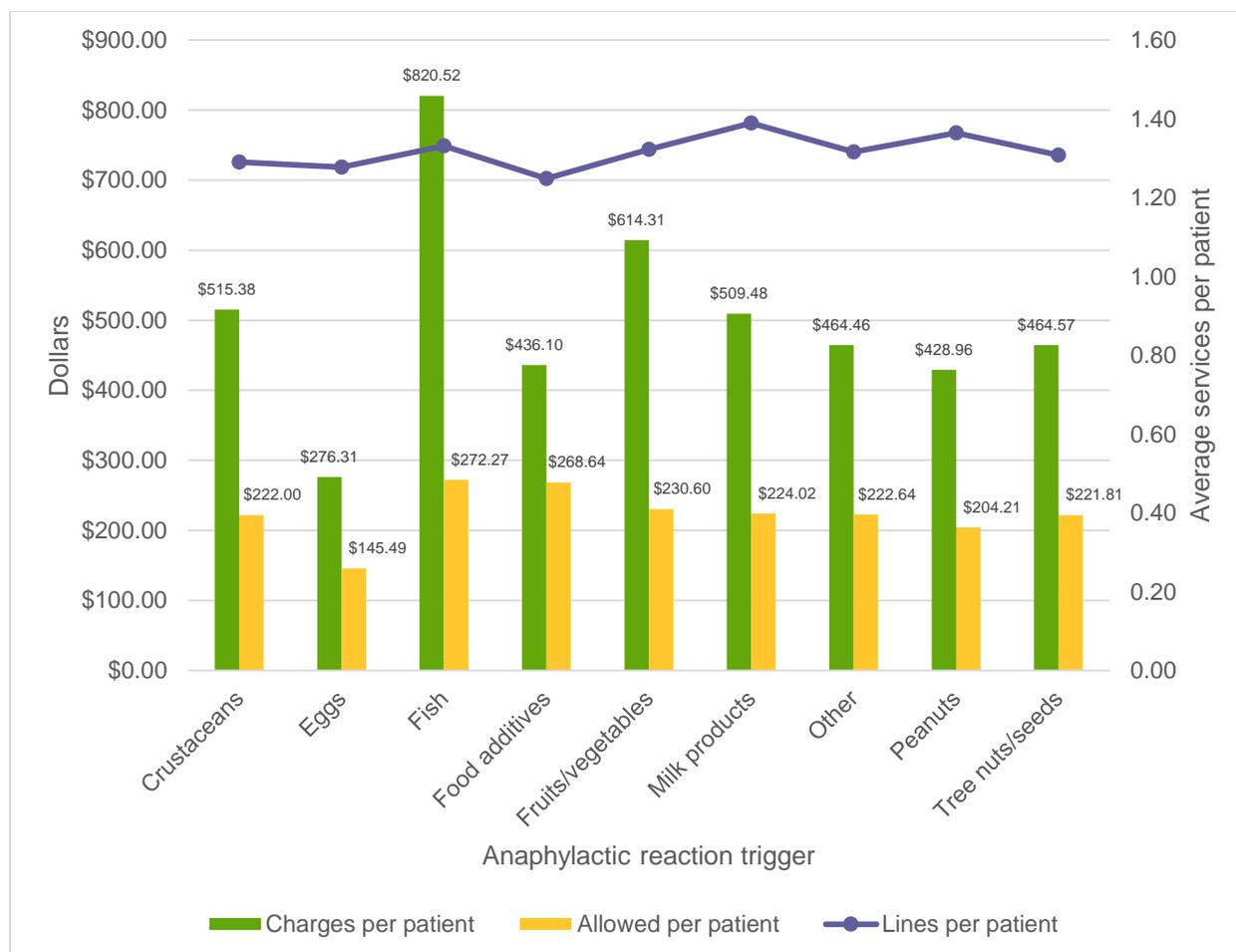


Figure 26. Average annual costs and services per patient diagnosed with anaphylactic food reaction, by trigger, 2016. “Lines” are “services.”

Conclusion

This analysis by FAIR Health is consistent with findings of other studies that food allergy is increasing. Furthermore, it has shown the states in which the increase appears to have been greatest, the higher growth in rural than urban areas and the excess in growth of claim lines with diagnoses of anaphylactic food reaction over those of food allergy. Also of note is the extent to which food allergy affects all age groups and both genders, in a pattern in which food allergy is seen more often in male patients in childhood and in female patients in adulthood. By looking into place of service, procedure code category and average costs and services per patient, this study emphasizes the impact of food allergy on the healthcare system. The office setting has been overwhelmingly utilized for diagnoses of anaphylactic food

³⁴ Food Allergy Research & Education (FARE), “Fish Allergy,” accessed October 5, 2017, <https://www.foodallergy.org/common-allergens/fish>.

reaction, but the costs have been disproportionately greater in other places of services. Office or outpatient services to an established patient was the largest category of procedure codes associated with both food allergy and anaphylactic food reaction. The food allergy with the highest costs and average services per patient in 2016 was milk product allergy, although, among anaphylactic food reactions, anaphylactic reaction to fish had the highest costs per patient that year. FAIR Health hopes that this research will be of interest to all healthcare stakeholders, including payors, providers, government agencies, policy makers and patient advocates, and that it will spark further research into this public health concern and how best to address it.

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About FAIR Health

FAIR Health is a national, independent, nonprofit organization dedicated to bringing transparency to healthcare costs and health insurance information through data products, consumer resources and health systems research support. FAIR Health possesses the nation's largest collection of private healthcare claims data, which includes over 24 billion claim records contributed by payors and administrators who insure or process claims for private insurance plans covering more than 150 million individuals. FAIR Health also holds separate data representing the experience of more than 55 million individuals enrolled in Medicare. Certified by the Centers for Medicare & Medicaid Services (CMS) as a Qualified Entity, FAIR Health receives all of Medicare Parts A, B and D claims data for use in nationwide transparency efforts. FAIR Health licenses its privately billed data and data products—including benchmark modules, data visualizations, custom analytics, episodes of care analytics and market indices—to commercial insurers and self-insurers, employers, hospitals and healthcare systems, government agencies, researchers and others. FAIR Health has earned HITRUST CSF and Service Organization Controls (SOC 2) certifications by meeting the rigorous data security standards of those organizations. As a testament to the reliability and objectivity of FAIR Health data, the data have been incorporated in statutes and regulations around the country and designated as the official, neutral data source for a variety of state health programs, including workers' compensation and personal injury protection (PIP) programs. FAIR Health data serve as an official reference point in support of certain state balance billing laws that protect consumers against bills for surprise out-of-network and emergency services. FAIR Health also uses its database to power a free consumer website available in English and Spanish and an English/Spanish mobile app, which enable consumers to estimate and plan their healthcare expenditures and offer a rich educational platform on health insurance. The website has been honored by the White House Summit on Smart Disclosure, the Agency for Healthcare Research and Quality (AHRQ), URAC, the eHealthcare Leadership Awards, appPicker, *Employee Benefit News* and *Kiplinger's Personal Finance*. FAIR Health also is named a top resource for patients in Elisabeth Rosenthal's book, *An American Sickness: How Healthcare Became Big Business and How You Can Take It Back*. For more information on FAIR Health, visit fairhealth.org.

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