2016

The Ever-Changing World of Life Sciences

YEAR-END REPORT

PORZIO LifeSciences

Contents

GREETINGS

Customers and Colleagues:

We at Porzio Life Sciences ("PorzioLS") have been a leading resource for the life sciences industry for over 12 years. As such, we have been front and center for the exciting changes that continue to drive the evolution of the industry. We proudly offer the 2016 **Porzio Life Sciences Year-End Report** as an overview of many of the year's key events.

2016 proved to be another exciting and challenging year for the life sciences industry:

- Several counties in California passed ordinances for drug stewardship programs, while Massachusetts became the first state to pass drug stewardship legislation.
- Many states have made moves to comply with the Drug Supply Chain Security Act ("DSCSA"), which prohibits states from licensing third-party logistics providers ("3PLs") as wholesale distributors. A number of these states have revised their laws and/or regulations to provide separate licensing requirements for 3PLs.
- New Jersey enacted legislation clarifying that Food and Drug Administration ("FDA") approval is not necessary prior to New Jersey issuing a manufacturer registration to applicants. This legislation also sets time limits for the state to review registration applications.
- In 2016, EFPIA member companies were required to publicly disclose, for the first time, transfers of value to HCPs and healthcare organisations.
- The Centers for Medicare and Medicaid Services ("CMS") published the 2015 Open Payments data submitted and attested to by applicable manufacturers and group purchasing organizations ("GPOs").
- In 2016, many states introduced and/or enacted legislation requiring life sciences companies to report costs related to marketing and advertising their drugs to consumers and prescribers. Many states also introduced and/or enacted legislation requiring companies to report information related to increases in their drug prices.

We hope that this report serves as a useful reference of 2016 key events, and provides meaningful, practical information to you and your company. We thank you for your continued trust in PorzioLS for your regulatory and compliance challenges, and wish you a successful new year.

Sincerely,

The Porzio Life Sciences Team

LICENSING AND DISTRIBUTION

Drug Stewardship Programs

DRUG TAKE-BACK PROGRAMS: LOCAL GOVERNMENTS

Several counties in California have enacted ordinances requiring pharmaceutical manufacturers to finance and operate drug stewardship programs for the collection, transport, and disposal of unwanted drugs. These include the counties of Alameda, Marin, San Mateo, Santa Barbara, and Santa Clara, the County and City of San Francisco, and the County and City of Santa Cruz. King County and Snohomish County in Washington and Cook County in Illinois have also passed similar requirements.

DRUG TAKE-BACK PROGRAMS: STATE GOVERNMENTS

Massachusetts: In March 2016, Massachusetts became the first state to pass drug stewardship legislation.

New York: In May 2016, the New York State Assembly introduced drug stewardship legislation similar to the legislation passed by Massachusetts. This bill died at the end of 2016.

Massachusetts Drug Stewardship Legislation

THE LAW

Effective January 1, 2017, any pharmaceutical manufacturer selling or distributing a covered drug to consumers in Massachusetts, directly or through a wholesaler, retailer or other agent, is required to:

- Finance and operate a drug stewardship program, either individually or jointly with other manufacturers, approved by the Massachusetts Department of Health ("Department"); or
- Enter into an agreement with a stewardship organization to operate a Department-approved drug stewardship program.

PLAN REQUIREMENTS

Each plan must meet the following requirements:

Collection System: Provisions for convenient, ongoing collection services to all persons seeking to dispose of unwanted drugs. The collection system is to include two (2) Department-recommended methods such as:

- A mail-back program with prepaid and preaddressed packaging for a pharmacy to distribute when filling a prescription for a covered drug or upon request by a consumer;
- Collection kiosks;
- Drop-off day events at regional locations;
- In-home disposal methods;
- Any other method recommended pursuant to DEA guidelines.

Security: Provisions for adequate security of unwanted drugs and the safety of any person involved in monitoring, staffing, or servicing the stewardship program throughout the collection process.

Education: A plan for public outreach and education about the drug stewardship program.

Costs: A plan for the manufacturer or stewardship organization that provides the operational and administrative costs associated with the program. Point-of-sale, point-of-collection, processing fees, or other drug cost increases may not be charged to individual consumers to recoup program costs.

Compliance: An attestation that the program complies with all applicable state and federal requirements for the collection, security, transport and disposal of drug products, including any requirements established by rule or regulation of either the DEA or the EPA.

ANNUAL REPORT

Each operator of a drug stewardship program must file an annual written report to the Department describing the program's activities for the prior year and the volume and type of unwanted drugs collected no later than March 1st of each year.

Key Terms

COVERED DRUGS

Schedule II or III brand name or generic opioid drugs include benzodiazepines

DEPARTMENT

Massachusetts Department of Public Health

DRUG STEWARDSHIP PROGRAM

A program financed by a pharmaceutical product manufacturer or a group of manufacturers to collect, secure, transport, and safely dispose of unwanted drugs

PHARMACEUTICAL PRODUCT MANUFACTURER

An entity that manufactures a controlled substance under a FDA manufacturer's license, except for an institutional pharmacy or a wholesaler

STEWARDSHIP ORGANIZATION

An organization designated by a manufacturer or group of manufacturers to act on their behalf to implement and operate a drug stewardship program

Implementing the Drug Supply Chain Security Act

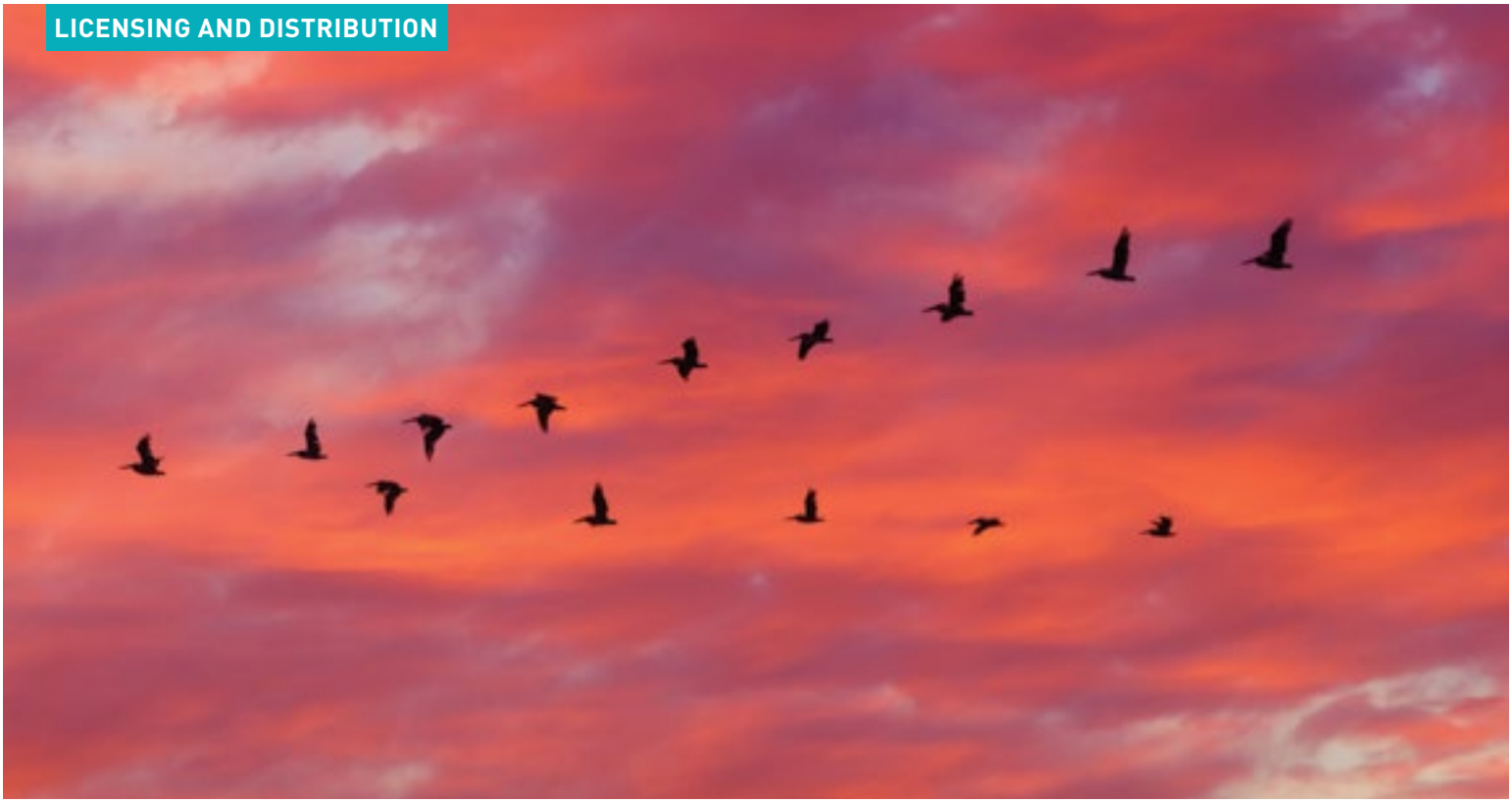
The Drug Quality and Security Act amends the Federal Food, Drug, and Cosmetic Act. Title II of the Act, also known as the Drug Supply Chain Security Act ("DSCSA"), requires the U.S. Food and Drug Administration ("FDA") to establish uniform standards for licensing of wholesale drug distributors and third-party logistics providers ("3PLs"). The DSCSA also requires wholesale drug distributors to be licensed by the state from which their drug is distributed, or by the Secretary of Health and Human Services ("Secretary") if the state from which the drug is distributed has not established licensure requirements.

Further, the DSCSA requires 3PLs to be licensed by the State from which the drug is distributed by the 3PL, or by the Secretary if the state from which the drug distributed has not established a licensure requirement. Shortly after the DSCSA was passed, the FDA published a DSCSA Implementation Plan with estimate target dates for it to issue guidances and/or regulations to implement various sections of the law. Although the Implementation Plan indicated that it would develop and release regulations establishing standards for licensing of wholesale drug distributors and 3PLs by November 27, 2015, the FDA indicated in June 2016 that it will not publish proposed regulations until December 2016.

Making Moves: Update on Third-Party Logistics Provider Licensing

To date, the FDA has not published proposed regulations. Many states, however, have made moves to revise their laws and/or regulations to conform with the DSCSA provision that prohibits states from regulation and licensing 3PLs as wholesale distributors. The following states have made moves to comply with the DSCSA. Many of these states previously treated 3PLs as wholesale distributors.

- ALABAMA
- ARKANSAS
- CALIFORNIA
- FLORIDA
- GEORGIA
- ILLINOIS
- LOUISIANA
- MISSISSIPPI
- NEBRASKA
- NEW HAMPSHIRE
- NORTH CAROLINA
- NORTH DAKOTA
- OHIO
- OKLAHOMA
- OREGON
- SOUTH CAROLINA
- TENNESSEE
- UTAH
- VIRGINIA
- WEST VIRGINIA



The Logistics: Key Changes

ALABAMA

On August 30, 2016, the Alabama Board of Pharmacy issued a notice indicating that it will provide separate permits for 3PLs.

GEORGIA

Effective July 1, 2016, 3PLs must register with the Georgia Board of Pharmacy prior to operating in the state. Out-of-state 3PLs, licensed by their resident state or by the FDA, are not required to register with the Board.

ILLINOIS

The Department of Financial and Professional Regulation instructed 3PLs not to complete the wholesale distributor application so as to comply with the DSCSA. At this time, the Department does not have a separate license for 3PLs.

MISSISSIPPI

Effective July 30, 2016, the Mississippi Board of Pharmacy amended its regulations, which changed the "drug wholesaler permit" to the "drug facility permit" and defined 3PLs. In November 2016, the Board issued a notice on new permit types including 3PLs.

NEBRASKA

On July 1, 2016, manufacturer and 3PL licenses were allowed to expire, and renewal was not required. The Nebraska Department of Health and Human Services no longer requires a state license for manufacturers or 3PLs.

NEW HAMPSHIRE

The Wholesale Distributor Application for Permit was revised in April 2016, and included a note that 3PLs will be licensed under a separate category for the 2016-17 licensing period.

OHIO

Effective April 1, 2016, 3PLs must be licensed as a wholesale distributor with a 3PL classification.

UTAH

Effective December 22, 2016, the Utah Board of Pharmacy amended its regulations, and changed the license classification for 3PLs from Pharmacy Class C (Pharmaceutical Wholesalers) to Pharmacy Class E.

VIRGINIA

Effective July 1, 2016, 3PLs must obtain a permit from the Virginia Board of Pharmacy in order to operate in the state.

WEST VIRGINIA

Effective July 1, 2016, the West Virginia Board of Pharmacy established separate licensing requirements for 3PLs.

New Jersey Enacts Legislation Clarifying That FDA Approval Is Not Necessary Prior to Manufacturer Registration

On December 5, 2016, New Jersey Governor Chris Christie signed into law Porzio-supported legislation. As a result, product approval from the U.S. Food and Drug Administration ("FDA") is no longer a condition for a pharmaceutical company to receive registration approval by the State Department of Health. As registration in a company's home state is one of the necessary first steps in the process for a new drug to be brought to market, the requirement imposed by the State Department of Health was particularly burdensome on companies based in New Jersey. This legislation further requires the Department of Health to review registration statements and reply to the registrant within 30 days of receipt.

PorzioLS and Porzio Governmental Affairs, LLC initiated the introduction of this legislation by Senators Fred H. Madden, Jr. (D-Gloucester) and Steven V. Oroho (R-Sussex) and Assemblyman Tim Eustace (D-Bergen). Designated as S2024/A3793, the legislation passed both houses of the legislature unanimously before heading to the Governor's desk.

Frank Fazio, Porzio Principal and PorzioLS Vice President of Distribution and Licensing Services, testified in support of S2024 before the New Jersey Senate Health, Human Services and Senior Citizens Committee, and before the Assembly Health and Senior Services Committee in support of A3793. Prior to the introduction of the legislation, he brought the issue before the Red Tape Review Commission in September of 2015, outlining the obstacles being faced by biotech companies with the existing registration process.

Lobbying efforts were spearheaded by Porzio Government Affairs Executive Vice President Lynn Nowak. Porzio is proud to support our clients' goals and to be able to enact significant changes that will aid New Jersey businesses and industry going forward.

New Jersey Introduces Legislation To Prohibit Manufacturers From Providing Discounts, Rebates, or Product Vouchers for a Drug or Biologic If a Lower Cost, Therapeutically Equivalent Product Is Available

In November 2016, the New Jersey Senate introduced legislation that would prohibit manufacturers from offering any discount, rebate, product voucher, or other reduction in an individual's out-of-pocket expenses for certain prescription drug and prescription biological products. This prohibition would apply to any prescription drug or prescription biological for which a therapeutically equivalent or interchangeable product, as designated by the U.S. Food and Drug Administration ("FDA"), is available at a lower cost.

This prohibition would not apply to discounts, rebates, or other payments made by a manufacturer to a patient for health care items or services related to the patient's use of a prescription drug or biological product where the item or service "is required under a [FDA] Risk Evaluation and Mitigation Strategy or are for the purpose of monitoring or facilitating the use of the prescription drug or biological product in a manner consistent with the product's approved labeling."

If passed, this legislation would mirror currently enacted legislation in Massachusetts. Isolated instances or trend? We will look to learn more in 2017!

ENFORCEMENT ACTIONS

PhRMA and BIO Published Principles of Off-Label Communication

On July 27, 2016, the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO") jointly published the "Principles on Responsible Sharing of Truthful and Non-Misleading Information About Medicines with Healthcare Professionals and Payers." These guidelines were prompted in part by industry's need for greater flexibility when communicating with other individuals in the healthcare industry, such as payors. The nine principles acknowledge the importance of sound, scientific-based information beyond the parameters of an FDA-approved label and highlight the importance of such information, while focusing on appropriate context and audience for such data. The principles emphasize the necessity and integrity of scientific substantiation before communicating off-label information, as well as the financial and medical benefits to patients when off-label information is shared responsibly. Embedded in the principles are several suggestions to FDA about how the two industry groups think the Agency should permit greater flexibility in this area.

FDA Held Public Hearing on Off-Label Communication

FDA held a public hearing on November 9-10, 2016, to obtain comments on its regulation of off-label communications. The questions posed at the hearing, which were published in the Federal Register on September 1, 2016, sought feedback on a number of topics, including: how increased communications about unapproved uses could impact public health, the importance of scientific integrity of information, standards to minimize misleading communications, the quality and transparency of information regarding unapproved uses, and how to assess the risks and benefits of new uses of medical products. FDA is also seeking electronic and written comments to the questions posed in the Federal Register and recently extended the comment period to April 10, 2017.

OIG Published Final Rules on Anti-Kickback Safe Harbors and Civil Monetary Penalties

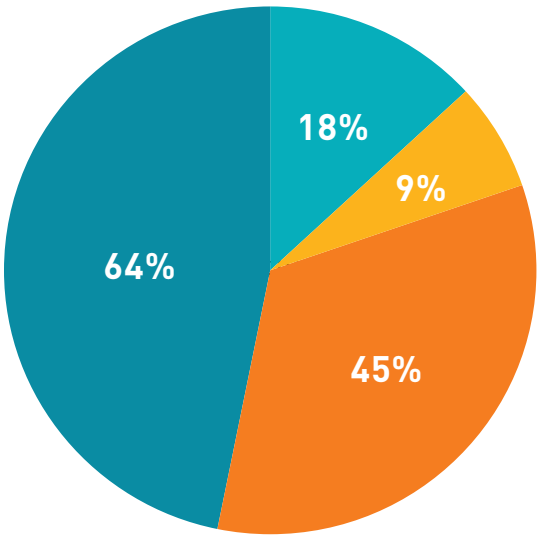
The Office of Inspector General ("OIG") published two new Final Rules on December 7, 2016. One of the rules expanded existing, and added new, safe harbors to the anti-kickback statute. The other reorganized the regulations governing the imposition of Civil Monetary Penalties ("CMP"), and provided greater detail on how CMPs are calculated, including a non-exhaustive list of aggravating and mitigating factors.

The expanded or new safe harbors will protect conduct in the following areas: (1) hospital cost-sharing waivers; (2) federally qualified health center ("FQHS") cost-sharing; (3) pharmacy cost-sharing waivers; (4) public ambulance cost-sharing waivers; (5) remuneration between FQHS and Medicare Advantage Plans; (6) the Medicare Coverage Gap Discount Program; and (7) free or discounted local transportation.

The Final Rule on CMPs reorganized the regulations into subparts by subject matter to make them more accessible to the public, and to add clarity to the regulatory scheme. Of the subparts, Subpart L (drug price reporting) contains the changes most relevant to pharmaceutical manufacturers. This Final Rule finalized OIG's proposed approach to calculate penalties at the National Drug Identifier (NDC) level for both the daily penalty for late reporting and the penalty for knowingly reporting false information, rather than per late report, which could contain multiple NDCs.

FDA's Office of Prescription Drug Promotion

Recent years have seen a steep decline in the number of enforcement letters issued by FDA's Office of Prescription Drug Promotion ("OPDP"). From a peak of 158 in 1998, the number of letters in 2016, quite small at eleven, exceeded 2015's all-time low of only nine. Despite fewer letters over the past few years, there is still much to be learned from the content of the communications and related FDA actions. Below is a chart depicting the violation categories cited in the letters by OPDP. The 2016 letters included eight Untitled Letters and three Warning Letters.



PERCENTAGE OF 2016 OPDP LETTERS CITING VIOLATION CATEGORY

- Minimization, Omission or Misleading Presentation of Risk Information
- Promotion of Intended Use for Which Drug Lacks Approval/ Labeling Lacks Adequate Directions for Use
- Broadening, Misinformation, or Inadequate Communication or Indication Use or Administration
- Failure to Submit Promotional Materials to FDA at Time of Initial Dissemination

CDRH Enforcement Letters have been added to PCD!

PorzioLS is pleased to announce that Porzio Compliance Digest ("PCD") now includes a searchable catalogue of letters issued by FDA's Center for Devices and Radiological Health ("CDRH") and the Office of Compliance addressing advertising and promotional violations relating to medical devices. The letters are summarized to provide subscribers with the most pertinent information, and links to the full letters are included for easy access. We are excited to offer this expanded functionality to our customers!

INTERNATIONAL TRANSPARENCY

A Milestone Moment (or a Dead Jellyfish) for the Global Transparency Movement

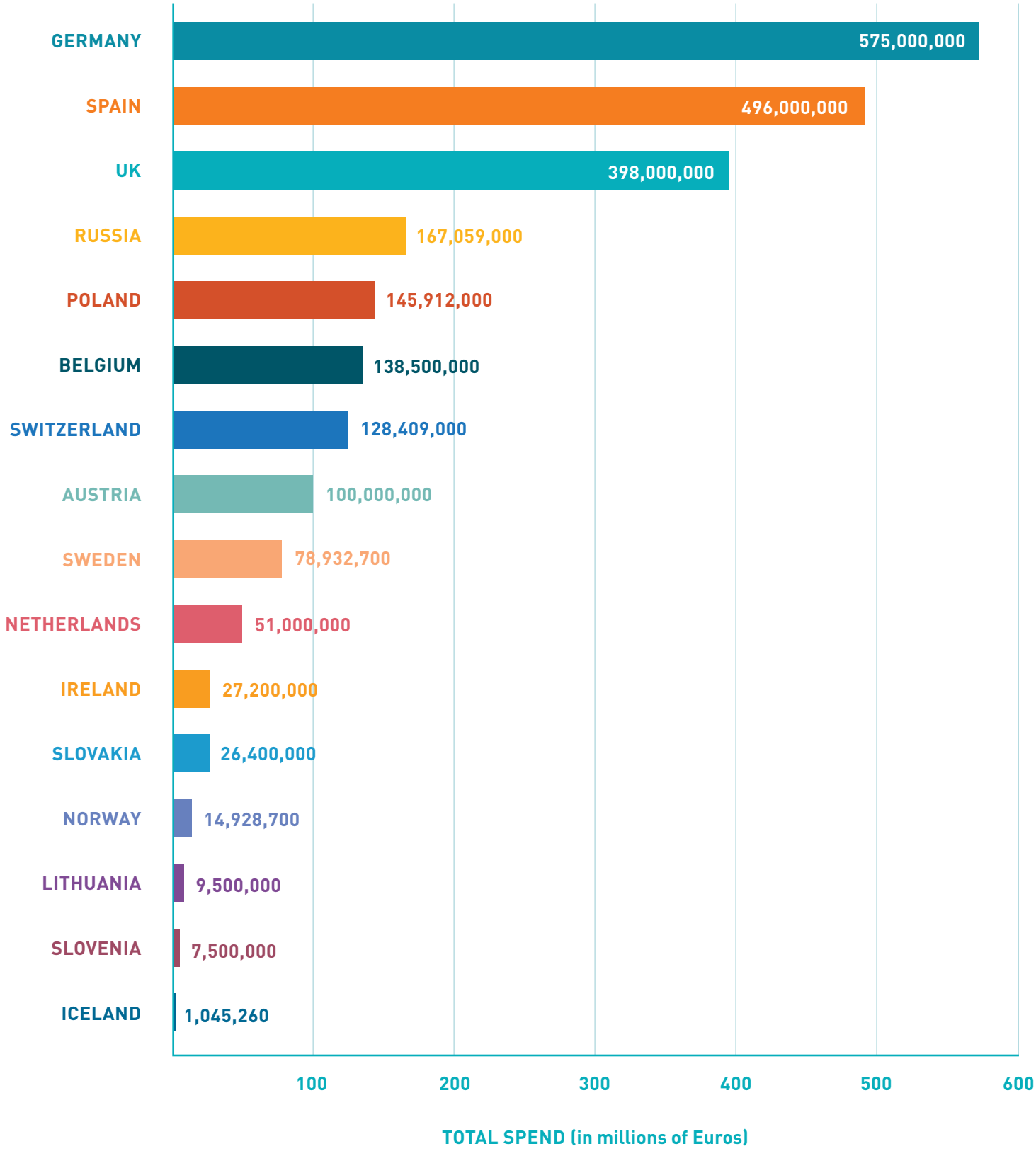
Under the European Federation of Pharmaceutical Industries and Associations' ("EFPIA") Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations ("Disclosure Code"), in 2016, EFPIA member companies were required to publicly disclose, for the first time, their 2015 transfers of value to healthcare professionals (HCPs) and healthcare organisations ("HCOs"). Companies must report, on the individual level, their transfers of value provided to HCPs and HCOs in the following categories: 1) donations and grants (for HCOs only); 2) contributions to costs related to events (including registration fees; travel and accommodation, to the extent permissible; and sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an event); and 3) fees for service and consultancy. Unlike in the United States, companies do not have to report the details of every single transaction that they have with a HCP or HCO; instead, they are permitted to aggregate all their transfers of value to a HCP or HCO on a category-by-category basis, so long as they are able to provide itemized disclosure upon the request of the recipient or the relevant authorities.

Although it is too soon to draw definitive conclusions about the long-term success and viability of the Disclosure Code, it is clear that the biggest issue that the pharmaceutical industry must confront is the consent issue, as most of the reaction from stakeholders, critics, and the press focused on the HCPs who did not consent to individual-level disclosure.

For several years, PorzioLS has published an annual White Paper focusing on EFPIA's progressive stance and motivations regarding code-based reporting. We previously speculated about how effective EFPIA's self-disclosure system would be, in terms of whether a significant portion of the market would report and whether HCPs would provide consent to individual-level disclosure. We also wondered how governments would react to the data that was reported and whether it would satisfy them or lead them to pass more transparency laws. Now, for the first time, we have actual data to discuss, as well as reactions to that data.

To read the full 2016 White Paper, "A Milestone Moment (or a Dead Jellyfish) for the Global Transparency Movement," by D. Jeffrey Campbell and Brian P. Sharkey, please ***click here***.

EFPIA 2016 Overall Total Spend by Country (in Euros)



2017 Projected Reporting Dates by Country

The following list presents the anticipated 2017 due dates for transparency reports as of December 31, 2016.*

**Reporting dates are subject to change. Please contact PorzioLS if you have questions.*

AUSTRALIA
February 28, 2017
(HCP/Third Party Report)
August 31, 2017
(HCP/Third Party Report)

BELGIUM
April 30, 2017 (EFPIA Report)

DENMARK
January 31, 2017 (Legislative Report)

EFPIA REPORTS
June 30, 2017

ESTONIA
February 1, 2017 (Legislative Report)
June 1, 2017 (EFPIA Report)

FINLAND
May 31, 2017 (EFPIA Report)

FRANCE
February 1, 2017 (Benefits Report)
August 1, 2017 (Benefits Report)

NETHERLANDS
February 19, 2017 (Legislative Report)

NORWAY
June 24, 2017 (EFPIA Report)

ROMANIA
March 31, 2017 (Legislative Report)

SLOVAKIA
June 17, 2017 (EFPIA Report)
July 31, 2017 (Legislative Report)

SPAIN
June 1, 2017
(Pre-disclosure EFPIA Report)

SWEDEN
May 31, 2017 (EFPIA Report)

UNITED KINGDOM
March 31, 2017 (EFPIA Report)

UNITED STATES
March 31, 2017 (Sunshine Act Report)

Recurring Reports

CANADA
Still in question

FRANCE
Within 15 calendar days
of agreement

JAPAN
End of a company's fiscal year

PORTUGAL
Within 30 calendar days
of granted transactions

InfoCenter

The PorzioLS InfoCenter Update is a dynamic tool designed to provide alerts on topics critical to life sciences companies, including issues related to product marketing and sales, U.S. and ex-U.S. transparency reporting compliance, wholesale distributor and manufacturer licensing and distribution requirements, PDMA compliance, and U.S. enforcement actions.

If you have any questions on how you may receive access to the InfoCenter Update, please visit porziolifesciences.com or contact us at 877.477.7411.

Porzio GST®

Porzio Life Sciences developed Porzio GST® to meet our customers' goals of implementing an ex-US platform for transparency reporting. This solution facilitates data collection and transparency reporting for Japan, Australia and all European jurisdictions and addresses the challenges surrounding cross-border spend, HCP consent, data privacy, and global language and currency distinctions, to facilitate efficient and accurate reporting.

For more information about Porzio GST®,
please call 973-538-1690 or visit www.PorzioLifeSciences.com.

MID-LEVEL REGULATIONS

Key Changes for Mid-Level Professionals

KEY: Introduced | Passed | * Controlled substances prescriptive authority changes

FLORIDA*

Effective **January 1, 2017**, ARNPs and physician assistants will be permitted to prescribe, order, and administer controlled substances. Currently, ARNPs and PAs are not authorized to prescribe controlled substances.

IOWA*

Effective **July 1, 2016**, psychologists in Iowa may apply for a conditional prescription certificate to prescribe psychotropic medication under the supervision of a licensed physician. Previously, psychologists were not permitted to prescribe legend drugs or controlled substances. Iowa is the 4th state to allow psychologists to prescribe.

MASSACHUSETTS

On **June 13, 2016**, the Massachusetts Senate introduced legislation that would establish the Board of Registration in Naturopathy. Currently, Massachusetts does not formally recognize naturopathic doctors. This bill is still pending.

MICHIGAN*

On **November 10, 2016**, the Michigan House of Representatives introduced legislation that would impose a 7-day supply restriction on prescriptions for opiates when issued to an adult for the first time, or to minors. This bill is still pending.

NEW YORK

Effective **July 22, 2016**, all prescriptions for a Schedule II, III, or IV opioid are restricted to a 7-day supply when issued to an adult for the first time.

OHIO

On **February 10, 2016**, the Ohio Senate introduced legislation to eliminate the requirement that an APRN practice in accordance with a standard of care arrangement with a licensed physician. Additionally, APRNs would no longer be required to obtain a Certificate to Prescribe prior to prescribing drugs and therapeutic devices. This bill is still pending.

PENNSYLVANIA

On **November 3, 2016**, the Governor of Pennsylvania signed legislation to create the Naturopathic Doctor Registration Act and provide for the registration of naturopathic doctors. Currently, the state of Pennsylvania does not formally recognize naturopathic doctors. This approved legislation will become effective on January 1, 2018.

TEXAS

Effective **September 1, 2016**, practitioners are no longer required to obtain a State Controlled Substances Registration prior to prescribing or dispensing controlled substances.

WASHINGTON

Effective **April 30, 2016**, a clinical nurse specialist is a recognized specialty designation of the title ARNP.

WEST VIRGINIA

Effective **June 11, 2016**, qualified APRNs may apply to prescribe drugs without a collaborative agreement after completing at least 3 years in a collaborative relationship with a licensed physician. Please note that APRNs must continue to prescribe controlled substances pursuant to an exclusionary formulary.

U.S. TRANSPARENCY AND LIMITATIONS

Sunshine Act Statistics: 2015 Open Payments Data

According to the Sunshine Act, applicable manufacturers of covered drugs, devices, biological products, and medical supplies must report annually certain information regarding payments and other transfers of value to physicians and teaching hospitals. An additional provision requires applicable manufacturers and group purchasing organizations ("GPOs") to report all ownership and investment interests held by physicians or members of their families. The Sunshine Act requires that the reported data be made available to the public on an Internet website that is searchable, clear, and understandable.

On June 30, 2016, the Centers for Medicare and Medicaid Services ("CMS") published the 2015 Open Payments data submitted and attested to by manufacturers and GPOs. The information included newly submitted 2015 data as well as updated payment records for 2013 and 2014.

According to CMS, manufacturers reported $7.33 billion in payments and ownership and investment interests to physicians and teaching hospitals. This amount is comprised of 11.91 million total records attributable to 618,000 physicians and 1,111 teaching hospitals.

Highlights from the CMS Published 2015 Data (as of February 9, 2017):

Total U.S. Dollar Value	$7.33 Billion
General Payments Disputed / Undisputed (USD)	$3.49 Million / $2.59 Billion
Research Payments Disputed / Undisputed (USD)	$5.50 Million / $3.89 Billion
Ownership or Investment Disputed / Undisputed (USD)	$28.78 Million / $803.44 Million

Total Records Published	11.91 Million
General Payments Disputed / Undisputed (Number of Records)	1,674 / 11.14 Million
Research Payments Disputed / Undisputed (Number of Records)	429 / 762,000
Ownership or Investment Interest Disputed / Undisputed (Number of Records)	3 / 4,316

APPLICABLE MANUFACTURERS AND GROUP PURCHASING ORGANIZATIONS	
Total AMs and GPOs Making Payments	1,455
General Payments (USD)	$2.60 Billion
Research Payments (USD)	$3.90 Billion
Value of Ownership or Investment Interest (USD)	$832.22 Million

PHYSICIANS AND TEACHING HOSPITALS	
Total Physicians with Payment Records	618,000
General Payments (USD)	$1.99 Billion
Research Payments (USD)	$85.58 Million*
Value of Ownership or Investment Interest (USD)	$832.22 Million

Total Teaching Hospitals with Payment Records	1,111
General Payments (USD)	$602.41 Million
Research Payments (USD)	$719.35 Million
Value of Ownership or Investment Interest	N/A**

The CMS Open Payments Data Website allows users to search and explore the data using various tools to create charts and graphs and prepare custom reports. Users have the ability to download and review the entire data sets, use the data explorer tool to create visualizations such as charts and graphs and to aggregate and filter data and use the search tool to find information on specific physicians, teaching hospitals and on the companies making payments.

*The physician research payments total includes: 1) Payments where the company making the payment has named a physician as the primary recipient, and 2) Payments to a research institution or entity where a physician is named as a principal investigator on the research project (i.e., received associated research funding).

**Ownership or investment interest is not applicable to Teaching Hospitals.

PorzioLS recognizes that there is a discrepancy in the research payments dollar figures.
We have reached out to CMS to confirm the numbers, but have not received a response as of the Year-End Report's publication.

Price and Cost Transparency

In 2016, many states introduced and/or enacted legislation requiring life sciences companies to either report costs related to marketing and advertising their drugs to consumers and prescribers, or report information related to increases in drug prices. The following states have introduced and/or enacted these types of law in 2016:

KEY: Introduced / Passed

- CALIFORNIA
- CONNECTICUT
- MINNESOTA
- NEW JERSEY
- NEW YORK
- RHODE ISLAND
- TENNESSEE
- VERMONT
- VIRGINIA
- WASHINGTON

VERMONT (ENACTED JUNE 3, 2016)

Vermont's Pharmaceutical Cost Transparency Act ("Act") requires the Green Mountain Care Board ("Board") to identify annually up to fifteen (15) prescription drugs from different drug classes that have a wholesale acquisition cost ("WAC") that has increased by 50% or more in the past five years, or by 15% over the past twelve months. Manufacturers of the identified drugs must report to the Attorney General's Office information relevant to the drug's WAC cost increase, including:

- The current wholesale acquisition cost price.
- The total WAC price increase over the past five years or the past 12 months (whichever time period is the basis for the Board's selection of the drug as a report subject). For each selected drug, the Board will state the relevant time period.
- An explanation of each factor that contributed to the increase, the percentage of the increase attributed to each factor, and an explanation of the role of each factor to the increase.

The first report was due by October 1, 2016. In December 2016, the AG's Office released the "Report of Attorney General to the Legislature Regarding Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635" ("Report"). The Report includes a summary of the information received from manufacturers of the ten drugs identified by the Board. Click here to view the Report.

CONNECTICUT (ENACTED JUNE 10, 2016)

On June 10, 2016, the Governor of Connecticut signed legislation establishing a task force to study the value-based pricing of prescription drugs. Members of the Senate and House of Representatives were required to appoint individuals to the task force within thirty days of the effective date of this legislation. The task force is required to submit a report of its findings and recommendations relating to consumer protection, insurance and public health to the joint standing committee of the General Assembly not later than January 1, 2017. To date, the task force has not yet been formed.

Chicago Adopts Licensing Ordinance for Pharmaceutical Representatives

On November 16, 2016, the City Council of Chicago, Illinois adopted amendments to the City's Management Ordinance ("Ordinance") that will require licensure of pharmaceutical representatives. As adopted, no person will be permitted to conduct business as a pharmaceutical representative in the City of Chicago without first having obtained a pharmaceutical representative license. The term "pharmaceutical representative" is "a person who markets or promotes pharmaceuticals to health care professionals."

Pharmaceutical representatives conducting business in the City for fewer than fifteen (15) days per calendar year will not be required to obtain a license. Prior to obtaining an initial license, pharmaceutical representatives will be required to complete a professional education course as determined by the Commissioner of Public Health ("Commissioner"). The fee for a pharmaceutical representative license will be $750 every two years.

The Ordinance requires the Commissioner to establish by rule continuing education requirements as a condition for an initial or a renewal pharmaceutical representative license. At minimum, all pharmaceutical representatives will be required to complete five (5) hours of continuing professional education prior to renewing their licenses. Additionally, the Ordinance requires pharmaceutical representatives, upon request or at time intervals prescribed by the Commissioner, to provide the following information to the Commissioner:

1. A list of health care professionals contacted and the number of times each health care professional was contacted;
2. The location and duration of the contact;
3. The pharmaceuticals promoted;
4. Whether product samples, materials, or gifts of any value were provided to the health care professional, and the value of the products, materials, or gifts; and
5. Whether and how the health care professional was compensated for contact with the pharmaceutical representative.

Further, the Ordinance requires the Commissioner to establish a list of ethical standards for pharmaceutical representatives and incorporate the list into the rules. In addition to these rules, pharmaceutical representatives will be prohibited from engaging in deceptive or misleading marketing of pharmaceutical products, including the knowing "concealment, suppression, omission, misleading representation, or misstatement of any material fact." Pharmaceutical representatives will also be prohibited from using a title or designation that could lead a licensed health professional to believe that the pharmaceutical representative is licensed to practice "medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation, in [Chicago], unless the pharmaceutical detailer currently holds such a license." Further, pharmaceutical representatives will be prohibited from attending patient examinations without the consent of the patient.

The amendments to the Ordinance will become effective July 1, 2017.

The New Kid on the Block: The First Disclosure Reports for Connecticut Will Be Filed in 2017

In 2015, Connecticut enacted legislation requiring applicable manufacturers that provide payments or other transfers of value to Advanced Practice Registered Nurses ("APRNs") engaged in independent practice to submit annual reports to the Connecticut Commissioner of Consumer Protection. The first reports must be submitted by July 1, 2017, and annually thereafter, and should include payments or other transfers of value provided to APRNs during the preceding calendar year.

Connecticut's law also requires the Commissioner of Public Health to publish annually on the Department of Public Health's ("Department") website a list of APRNs who are authorized to engage in independent practice. The Department has published this list on its website; applicable manufacturers should use this list when determining whether information on payments or other transfers of value made to APRNs must be reported.

The Department of Consumer Protection has indicated that its Drug Control Division will accept reports in the format found on the Centers for Medicare and Medicaid Services' Open Payments website titled "2013-2015 CSV Sample File: General Payments [CSV]." In the coming year, PorzioLS will continue to work with Department representatives to obtain additional information regarding implementation of these reporting requirements.

D.C. Introduces Temporary and Emergency Legislation to Amend the Pharmaceutical Detailer Licensure Exemption

Pursuant to the District of Columbia Pharmaceutical Detailers Amendment Act of 2008 ("Act"), pharmaceutical manufacturer and labeler representatives that are engaged in the practice of pharmaceutical detailing in the District of Columbia must obtain a pharmaceutical detailer license. The District's Municipal Regulations define pharmaceutical detailing as "the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purpose of selling, providing information about, or in any way promoting a pharmaceutical product." The Act was amended in 2015 to provide a licensure exemption for individuals "engaged in the practice of pharmaceutical detailing for less than 30 consecutive days per calendar year."

In December 2016, the D.C. Council ("Council") enacted the Pharmaceutical Detailing Licensure Exemption Emergency Declaration Resolution of 2016 ("Emergency Resolution"). According to the Emergency Resolution, since the enactment of the amended Act in 2015, there has been some ambiguity in how to interpret and implement the "30 consecutive days" to determine whether an individual needs to obtain a pharmaceutical detailer license. As such, the Council resolved that removing the term "consecutive" would eliminate any ambiguity from the exemption.

Following the Emergency Resolution, on December 20, the Council introduced the Pharmaceutical Detailing Licensure Exemption Temporary Amendment Act of 2016 ("Temporary Act"), which would strike the phrase "30 consecutive days per calendar year" from the current law, and insert the phrase "30 days per calendar year" in its place. At the same time the Temporary Act was introduced, the Council also introduced the Pharmaceutical Detailing Licensure Exemption Emergency Act of 2016 ("Emergency Act"). The Emergency Act was transmitted to the Mayor on December 23, 2016, and was enacted on January 6, 2017. The Temporary Act was approved by the Council on January 10, 2017, and approved by the Mayor on February 10, 2017.

Although both the Emergency Act and the Temporary Act amend the current law in the same way, the Temporary Act will remain in effect for a longer period of time than the Emergency Act (220 days for the Temporary Act and 90 days for the Emergency Act). The Temporary Act will provide sufficient time for the Council to enact permanent legislation. It is not uncommon for the Council to concurrently introduce temporary and emergency legislation.