



THE HEALTH LAWYER

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INTERNET PHARMACIES: TRENDS, OPPORTUNITIES, AND RISKS

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Introduction

As tech-savvy consumers become increasingly comfortable obtaining healthcare via electronic means, criminal enterprises seek to capitalize on these new technologies and prey on consumers. In the world of e-health, nowhere is criminal action more prevalent than in the Internet pharmacy market. Although many U.S.-based brick-and-mortar pharmacies offer legitimate online platforms that comply with state and federal law, “rogue” actors abound. Most operate from abroad as part of massive pharmacy networks comprised of thousands of Web sites; these illegal Internet pharmacy networks ship unapproved, misbranded, and adulterated prescription drugs into the United States, often without requiring a valid prescription and without appropriate pharmacy licensure. At a minimum, these illicit pharmacies violate the Federal Food, Drug, and Cosmetic Act (“FDCA”)¹ and state pharmacy laws; however, they often violate other laws, including those related to the practice of

medicine, controlled substances, fraud, money laundering, and intellectual property rights.

This article provides an overview of state and federal laws governing Internet pharmacies; a description of the issues surrounding “Canadian” Internet pharmacies; a synopsis of state, federal, international, and private sector enforcement activities involving illegal online drug sellers; and a summary of next steps required to address this pervasive issue.

Current Statistics

According to industry experts, there are roughly 30,000 to 35,000 active Internet pharmacies, of which only four percent comply with applicable laws.² Of the remaining 96 percent that operate illegally, 92 percent overtly violate the law; for example, many sell unapproved prescription drugs without requiring a prescription.³ A 2018 report by the National Association of Boards of Pharmacy (“NABP”) found that 54 percent of the online drug sellers analyzed offered controlled substances, and 40 percent offered oxycodone, Percocet, Xanax, or Norco, which are frequently counterfeited with fentanyl.⁴ This puts millions of Americans at risk of receiving dangerous counterfeit or otherwise illegal and unsafe medications, often

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Montrece McNeill
Ransom

Your Voice

In March of 2019, I was presented with the ABA Health Law Section (“HLS”)’s Champion of Diversity and Inclusion Award. I was incredibly honored to receive this particular award. I am, indeed, a champion for diversity and inclusion, and serving as a voice for

diversity is very important to me, both personally and professionally. I have been working in the field of public health law for almost 18 years, and I have long felt compelled to contribute to the creation of spaces where diverse individuals, regardless of their backgrounds and various identities, can feel included. I feel responsible for holding the door open for people who follow me. Receiving this award felt like recognition of my contributions to the ABA, and the HLS, and to our profession as a whole. I felt seen.

Through the years, I have actively recruited diverse members, ensured their involvement in the activities of the ABA HLS, and ensured that leadership opportunities were available to them. For example, in 2018 nine students of diverse backgrounds that I recruited joined the ABA, joined the HLS, and began service as student liaisons. One of those students was also the 2019 HLS Law Student Writing Competition winner, Madison Hartman. I have worked to provide increased leadership opportunities to diverse participants qualified to serve in those roles and have mentored diverse members as they’ve developed leadership pathways within the HLS. I have also promoted diversity and inclusion in the profession as a whole by doing things like serving as the only invited speaker at a career roundtable focused on health law at the 5th Annual HBCU Pre-Law Summit in September 2018.

Including people from diverse backgrounds, cultures, and experiences adds value. It means access to the widest range of perspectives, talents, and skills. Often that is where the focus ends – diversity and inclusion. However, there is a third, critical component and that is *belongingness*. A simple word, but a huge concept. Diversity and inclusion just do not work without it.

Let’s be clear – diversity is incredibly important in that it fosters innovation, and guards against stagnation

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shipped directly to U.S. patients from foreign sources that do not require a prescription.

The United States is the primary focus for illegal online drug sellers: 82 percent of Internet pharmacies are English-language Web sites and a similar number offer to ship prescription drugs to end-consumers in the United States.⁵ These efforts are successful: according to a 2012 Food and Drug Administration (“FDA”) survey, nearly one in four U.S. adult Internet consumers reported purchasing prescription drugs online.⁶ And that number is increasing – a more recent survey conducted in 2017 on behalf of the Alliance for Safe Online Pharmacies (“ASOP Global”) found that one-third of those surveyed had already purchased from an Internet pharmacy, and 55 percent reported that they have bought or would like to buy medicine online.⁷

Almost all illegal Internet pharmacy Web sites are affiliated with larger entities, commonly referred to as “networks,” that fulfill orders on their behalf. According to LegitScript, an Internet pharmacy verification and monitoring service, there are upwards of 150 illegal Internet pharmacy networks, and only three percent of Internet pharmacies operate outside these networks.⁸ As of 2016, a small number of networks control a large percentage of the illegal Internet pharmacy market. LegitScript has found that two networks, Rx-Partners and EvaPharmacy, together operate approximately 5,000 active Web sites, which is one-sixth of the Internet pharmacy market.⁹ Illicit Internet pharmacy networks are often lucrative enterprises. For example, Aff-Power, an illegal pharmacy network studied by researchers at the University of California, San Diego generated over \$126 million in revenue in a two-year period.¹⁰

Illegal Internet pharmacies pose a growing threat to public health and are directly tied to consumer harm. According to the Centers for Disease Control and Prevention (“CDC”), over 63,600 Americans died from drug overdoses in 2016, and almost two-thirds of those deaths were caused by opioids, which are readily available online.¹¹ A University of Southern California study found a connection between prescription drug abuse and Internet use: For every 10 percent increase in state high-speed Internet use, admissions to substance abuse treatment programs rose by approximately one percent.¹² Other studies have shown that consumers and healthcare providers cannot distinguish legitimate Internet pharmacies from rogue operators who sell substandard and counterfeit medicine. For example, in a recent study by the Purdue University College of Pharmacy, 89 percent of pharmacists claimed that they were not provided training on illegal Internet pharmacies, and 54 percent were unable to determine the legitimacy of illegal Internet pharmacies.¹³ In the ASOP Global study referenced above, 35 percent of consumers surveyed would accept moderate or high levels of risk when ordering from Internet pharmacies, which indicates the importance of protecting consumers from the online sale of counterfeit, substandard, and adulterated prescription drugs.¹⁴ Indeed, according to a report from the European Alliance for Access to Safe Medicines, 62 percent of medicines purchased online are counterfeit or substandard.¹⁵

Legitimate Internet Pharmacies

To operate legally in the United States, an Internet pharmacy must: (A) be licensed by the state board of pharmacy in the state where the patient is located *and* the state from

which the pharmacy dispenses drugs; (B) require a valid prescription based on a proper physician-patient relationship; and (C) sell only those prescription drugs that have been FDA-approved or meet an approval exemption. Examples of legitimate Internet pharmacies in the United States include the Web sites of chain and local community pharmacies, which often offer refill services online, and independent online shops like Pillpack and Healthwarehouse. As discussed above, however, the vast majority of Internet pharmacies fail to meet one or more of these basic requirements. A breakdown of each requirement follows.

Pharmacy Licensure

States regulate the practice of pharmacy through licensure requirements determined by state pharmacy boards. To operate legally in the United States, an Internet pharmacy must be: (1) licensed by the state board of pharmacy in the jurisdiction where the pharmacy is physically located; and (2) with the exception of Massachusetts, licensed by the state board of pharmacy in the jurisdiction where the patient resides.¹⁶ This second requirement will soon be universal: the Massachusetts Board of Pharmacy is in the process of approving regulations that will require out-of-state pharmacies to obtain “non-resident drug store pharmacy” licenses.¹⁷

Several states have crafted specific regulatory requirements for pharmacies that fill prescriptions via the Internet. For example, Florida requires Internet pharmacies not otherwise licensed in Florida to obtain an “Internet pharmacy permit” to sell prescription drugs to state residents.¹⁸ Other states, including Indiana, Kentucky, and Virginia, require Internet pharmacies to receive and display a NABP Verified Internet Pharmacy Practice Site (“VIPPS”) seal of approval

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or a state-approved equivalent.¹⁹ Texas requires its state board of pharmacy to post “a list of all Internet pharmacies licensed by the board [along with] information about each pharmacy, including the pharmacy’s name, license number, and state of physical location” on its Web site.²⁰ Some states, including Delaware, Florida, and Nevada, classify violations of their Internet pharmacy laws as felonies.²¹

Several states have attempted to license or authorize Canadian pharmacies to ship prescription drugs to state residents; however, because these efforts require Canadian pharmacies to import prescription drugs into the United States, they have been found to violate federal law regarding drug approval (described more fully below). For example, a 2005 Texas law required the Texas Board of Pharmacy to “inspect and authorize Canadian pharmacies to import prescription medications into the State of Texas;”²² however, in an opinion letter, the Texas Attorney General found that the Texas law directly conflicted with federal law.²³ More recently, Maine passed an amendment to the Maine Pharmacy Act that permitted licensed pharmacies in Australia, Canada, New Zealand, and the United Kingdom to forgo Maine pharmacy licensure and to “export prescription drugs by mail or carrier to a resident of [Maine] for that resident’s personal use.”²⁴ A federal judge struck down the Maine law in 2015, finding that the amendment’s true intent – to enable importation of certain cheaper foreign pharmaceuticals – infringed on the federal government’s authority under the FDCA.²⁵

Valid Prescription

Legitimate pharmacies dispense prescription medication only pursuant to a “valid prescription” as that term is defined in state law and, with respect to prescription drugs that

contain controlled substances, federal law.

State Law

For a prescription to be “valid,” states require a proper physician-patient relationship. To meet the standard of care required for this relationship, many states require that the physician perform an in-person examination;²⁶ however, an increasing number of states allow the use of telehealth in conducting the exam, where the provider can accurately diagnose and treat the patient while meeting the appropriate standard of care.²⁷ For example, in New Hampshire, a physician-patient relationship must include “an in-person or face-to-face 2-way real-time interactive communication exam.”²⁸

Many states specifically prohibit physician prescribing based solely in response to an online questionnaire, a practice common to illegal Internet pharmacies.²⁹ Regulatory language prohibiting this type of prescribing is found in state medical practice laws or state pharmacy laws, or in both. For example, Florida’s medical practice regulations state that “[p]rescribing medications based solely on an electronic medical questionnaire constitutes the failure to practice medicine with that level of care, skill, and treatment which is recognized by reasonably prudent physicians as being acceptable under similar conditions and circumstances.”³⁰ Alabama’s pharmacy regulations require that a pharmacist “not dispense a prescription drug if the pharmacist has knowledge, or reasonably should have known under the circumstances, that the order for such drug was issued on the basis of an Internet-based questionnaire, an Internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.”³¹ In Arkansas, “in the absence of a prior and proper patient-practitioner relationship,

‘prescription order’ does not include an order for a prescription-only drug issued solely in response to [an] Internet questionnaire.”³² In Vermont, a prescription is not valid unless it is issued for a “legitimate medical purpose,” and “issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship, does not constitute a legitimate medical purpose.”³³

There is one notable exception. In Utah, the Online Prescribing, Dispensing, and Facilitation Licensing Act³⁴ specifically permits Utah-licensed pharmacies to dispense a limited number of medications³⁵ on the basis of a prescription issued by a Utah-licensed physician pursuant to an online “branching” questionnaire;³⁶ however, the physician, pharmacy, and “internet facilitator” must all be licensed by Utah’s Online Prescribing, Dispensing, and Facilitation Licensing Board.³⁷

Federal Law

In 2008, Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act (“Ryan Haight Act”), named for an 18-year-old honors student and athlete who died after overdosing on Vicodin, an opioid that he obtained online from a physician he had never met.³⁸ Under the Ryan Haight Act, “[n]o controlled substance that is a prescription drug as determined under the [FDCA] may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.”³⁹

The Ryan Haight Act defines a “valid prescription” as a “prescription that is issued for a legitimate medical purpose in the usual course of professional practice by – (i) a practitioner who has conducted at least one in-person medical evaluation of the patient; or (ii) a covering practitioner.”⁴⁰ An “in-person medical evaluation” is further defined as a “medical evaluation

that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.”⁴¹

Although there are seven exceptions to the in-person medical evaluation requirement for the “practice of telemedicine,” these exceptions are limited.⁴² The most common “practice of telemedicine” exception occurs where the patient is physically located in a Drug Enforcement Administration (“DEA”)-registered hospital or clinic while being treated via telemedicine by a DEA-registered provider located off-site. In 2016, the DEA announced plans to activate a special registration process allowing physicians to use telemedicine to prescribe controlled substances without a prior in-person exam; however, as of 2018, the DEA had not acted. On October 24, 2018, President Trump signed into law the Special Registration for Telemedicine Act of 2018, which requires the DEA, within a year, to promulgate final regulations regarding the special registration process.⁴³

Note that the Ryan Haight Act applies solely to prescription drugs that contain controlled substances and does not apply to the majority of prescription drugs, which are not controlled.⁴⁴ Therefore, prescribing *non-controlled* drugs without performing an in-person examination may be clearly illegal in one state while ambiguous in another.

Drug Approval

The FDCA prohibits the interstate shipment, which includes foreign importation, of any drug that has not been approved for sale by the FDA or fails to qualify for an exemption from the approval requirements.⁴⁵

To maintain the safety and effectiveness of drugs in the U.S. supply chain, the FDA’s drug approval process extends far beyond approval of the drug’s active pharmaceutical ingredient. The FDA approves a

variety of factors, including manufacturing location, source of active ingredients, container/closure system, labeling, processing and shipping methods. Therefore, even if a drug is FDA-approved, the version produced for a foreign jurisdiction does not typically meet all FDA requirements for sale in the United States.⁴⁶ For this reason, FDA-approved drugs are often referred to as belonging to a “closed” supply chain. Drugs sold outside of this closed supply chain violate the FDCA because they are unapproved, misbranded, and/or adulterated. Misbranded drugs include those whose labeling is misleading or missing required information, such as adequate directions for use and FDA-mandated warnings; it also includes prescription drugs that are sold without requiring a proper prescription.⁴⁷ Adulterated drugs include those that differ in quality, strength, or purity from approved products, as well as those that are not manufactured in conformity with good manufacturing practices.⁴⁸ Unapproved drugs include drugs that have not gone through the FDA approval process.⁴⁹

A limited number of prescription drugs are exempt from requiring FDA approval. These include Drug Efficacy Study Implementation (“DESI”) drugs, grandfathered drugs, homeopathic drugs and compounded drugs. Although a discussion of FDA approval exemptions is outside the scope of this article, it is important to note that illegally imported drugs do not qualify for these exemptions.

In 1954, the FDA issued guidance regarding importation for “personal use.” The guidance acknowledged that, in limited circumstances, the FDA may allow individuals to import up to a 90-day supply of a drug for their personal use.⁵⁰ Illicit Internet pharmacies often cite this personal use guidance as blanket permission for U.S. residents to purchase a three-month supply of drugs from foreign online sellers; however, the conditions under which this guidance applies are

extremely limited. According to the FDA: “In most circumstances, it is illegal for individuals to import drugs into the United States for personal use. [...] For example, if a drug is approved by Health Canada (FDA’s counterpart in Canada) but has not been approved by FDA, it is an unapproved drug in the United States and, therefore, illegal to import.”⁵¹ To further narrow the scope of this guidance, the FDA set forth the following multifactor scenario in which the personal use guidance *may* apply:

The importation of certain unapproved prescription medications for personal use may be allowed in some circumstances if all of these factors apply:

- if the intended use is for a serious condition for which effective treatment may not be available domestically;
- if the product is not considered to represent an unreasonable risk;
- if the individual seeking to import the drug affirms in writing that it is for the patient’s own use and provides the name and address of the U.S.-licensed doctor responsible for his or her treatment with the drug or provides evidence that the drug is for continuation of a treatment begun in a foreign country;
- if the product is for personal use and is a three-month supply or less and not for resale, since larger amounts would lend themselves to commercialization; and
- if there is no known commercialization or promotion to U.S. residents by those involved in distribution of the product.

That means if you buy your high blood pressure or other medication from a foreign country because it’s cheaper – even though a drug with the same name is approved for sale in the United States – generally the drug will be considered unapproved and the FDA’s personal use guidance will not apply.⁵²

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In 2003, Congress passed legislation attempting to circumvent the FDA approval process and allow the importation of drugs from Canada. The Medicare Prescription Drug, Improvement, and Modernization Act authorizes the Secretary of Health and Human Services (“HHS”) to “promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.”⁵³ However, the Secretary of HHS must be able to certify that implementing the program will pose no additional risk to public health and safety, and will result in a significant reduction in the cost of drugs to the U.S. consumer.⁵⁴ To date, no Secretary of HHS has been able to certify that this is true, and therefore no Secretary has implemented these regulations.⁵⁵ Despite substantial political pressure to do so, it appears unlikely that the current HHS Secretary, Alex Azar, will promulgate regulations permitting the importation of prescription drugs from Canada into the United States. In 2018, Secretary Azar noted: “[T]he last four FDA commissioners have said there is no effective way to ensure drugs coming from Canada really are coming from Canada, rather than being routed from, say, a counterfeit factory in China. The United States has the safest regulatory system in the world. The last thing we need is open borders for unsafe drugs in search of savings that cannot be safely achieved.”⁵⁶

Several states have introduced bills that seek federal approval for plans allowing licensed wholesalers to import medicines from Canada and distribute them to pharmacies within their states.⁵⁷ In 2018, Vermont became the first state in the country to enact a drug importation law.⁵⁸ However, as of April 2019 Vermont regulators have not submitted an application to HHS to allow importation.⁵⁹

2019 has seen a flurry of congressional action regarding prescription

drug importation of non-FDA-approved medications. In January, Senator Bernie Sanders (I-VT) and Representatives Elijah Cummings (D-MD) and Ro Khanna (D-CA) introduced the Affordable and Safe Prescription Drug Importation Act, which would allow patients, pharmacists, and wholesalers to import medicine from Canada and other countries that meet certain requirements.⁶⁰ That same month, Senators Chuck Grassley (R-IA) and Amy Klobuchar (D-MN) and Representative Chellie Pingree (D-ME) proposed the Safe and Affordable Drugs from Canada Act of 2019, which would similarly permit the importation of prescription drugs from approved pharmacies in Canada.⁶¹ In response, over 100 advocacy organizations – representing law enforcement, healthcare professionals, patient advocates, and others – signed a letter stating their opposition to proposals to import non-FDA-approved medications. These groups cited concerns regarding patient safety, drug supply chain integrity, and exacerbation of the opioid crisis.⁶² Many other stakeholders, including state boards of pharmacies, nonprofit organizations, economists, academics, and others have also chimed in to oppose both direct-to-consumer and wholesale importation.

“Canadian” Internet Pharmacies

Because U.S. consumers often view Canadian pharmacies as safe and affordable alternatives to their U.S. counterparts, many illegal Internet pharmacies prominently display the Canadian flag and claim to operate from that jurisdiction. These Internet pharmacies are not licensed in the U.S. patient’s jurisdiction and do not dispense FDA-approved drugs. However, U.S. consumers often believe that these violations are immaterial, because they believe these sites sell

the same quality Health Canada–approved drugs to Americans that are sold to Canadian residents. Unfortunately, this is almost never true.⁶³

Some licensed Canadian pharmacies own and operate, or are otherwise affiliated with, Internet pharmacy Web sites that solely target U.S. consumers. These Web sites display a genuine Canadian pharmacy license, which leads U.S. residents to believe that the Canadian pharmacy is shipping Health Canada–approved medicine to the United States. However, the drugs are commonly sourced from sources located outside Canada – typically India, Turkey, or Southeast Asia. These foreign sources simply put the Canadian pharmacy’s information on the label to make U.S. consumers believe that the drugs are from Canada. In short, the drugs dispensed to U.S. consumers are not Health Canada–approved and are not the same quality drugs that a Canadian resident would receive from the same Canadian pharmacy.⁶⁴ The NABP has stated that it is unaware of any Canadian Internet pharmacies that consistently dispense Health Canada–approved medicines to U.S. consumers.⁶⁵ Similarly, Canadian pharmacy regulators⁶⁶ and drug regulators⁶⁷ have warned about the risks of these sites, including the potential for receiving counterfeit or otherwise illegitimate medicines marketed as Canadian.

To avoid running afoul of Canadian regulators, these licensed Canadian pharmacies typically dispense Health Canada–approved drugs to their Canadian customers. Indeed, their Web sites often “geo-target” U.S. consumers, and display only legitimate content when accessed from Canadian IP addresses.⁶⁸ However, when a pharmacy is based in Canada, the U.S. government cannot effectively exercise cross-border jurisdiction to ensure that the drugs shipped into the United States really

come from the actual Canadian pharmacy.⁶⁹

In addition to direct-to-consumer sales via the Internet, some Canadian pharmacies deliver unapproved and misbranded prescription drugs to U.S. consumers via brokers, who contract with U.S. employer-sponsored health insurance plans. In February 2019, the FDA issued a warning letter to CanaRx, a Canadian business that acts as a middleman between foreign pharmacies and U.S. employer-sponsored health insurance plans to provide enrolled employees with prescription drugs.⁷⁰ According to the FDA, CanaRx accepts the employee's U.S. prescription and facilitates its reissue under the direction of a foreign physician.⁷¹ CanaRx then substitutes FDA-approved drugs prescribed by the U.S. healthcare provider with foreign drugs that do not have the same assurance of safety and effectiveness as drugs subject to FDA oversight. FDA notes that these drugs may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain entirely different ingredients.

Despite jurisdictional difficulties, there have been several U.S. indictments involving Canadian pharmacies that shipped substandard and counterfeit drugs to the United States. For example, Andrew Strempler, a Canadian citizen and owner of RxNorth.com, falsely represented that RxNorth.com sold prescription drugs that complied with regulations in Canada, the United Kingdom, and the United States. In reality, RxNorth.com obtained prescription drugs from various other countries without ensuring their safety or authenticity, and sold counterfeit drugs to U.S. residents.⁷² In 2012, Mr. Strempler pled guilty; in 2013, he was sentenced to 48 months in prison and ordered to pay a forfeiture of \$300,000.⁷³

In another widely publicized case, the operators and wholesale affiliates of CanadaDrugs.com, a prominent Canadian Internet pharmacy, pled

guilty to illegally importing counterfeit Avastin, a chemotherapy drug, for sale and distribution to U.S.-based physicians and physician office practices.⁷⁴ According to reports, the counterfeit version was adulterated with corn starch and acetone, and contained no active pharmaceutical ingredient.⁷⁵ CanadaDrugs.com and its subsidiaries were sentenced to five years' probation, were fined \$5 million, and forfeited an additional \$29 million. The president of CanadaDrugs.com, Kristjan Thorkelson, was sentenced to six months' house arrest and five years' probation, and was fined \$250,000.⁷⁶ In addition, the Web site "canadadrugs.com" was seized by the United States government.⁷⁷

Other "Canadian" pharmacies have no connection to Canada. They do not work with a pharmacy or pharmacist licensed by a Canadian province and have no physical presence in Canada. Some illicit Internet pharmacies engage in "transshipment": They illegally import drugs in bulk to a western country likely to be viewed favorably by U.S. consumers (e.g., Canada, Germany, or the United Kingdom). However, these drugs are typically not approved by the regulatory authority in that jurisdiction and are often substandard.⁷⁸ These Web sites frequently require no prescription at all.

Enforcement

The vast majority of Internet pharmacies, including the so-called Canadian pharmacies discussed above, fail to meet one or more of the three requirements for legitimacy. Of the nearly 12,000 Internet pharmacies on the NABP's "not recommended" list, 23 percent are located outside the United States and therefore not properly licensed in any U.S. state.⁷⁹ Eighty-nine percent do not require a valid prescription.⁸⁰ Fifty-two percent offer foreign or non-FDA approved medication.⁸¹

Stopping these illegal actors requires a combination of federal,

state, international, and private sector enforcement.

Federal Enforcement

Because illegal Internet pharmacy networks are often comprised of thousands of affiliated Web sites operating from foreign jurisdictions, investigating and prosecuting them can be a herculean task requiring significant interagency cooperation and assistance from foreign governments. According to the U.S. Government Accountability Office ("GAO"):

[P]iecing together rogue Internet pharmacy operations can be difficult because they may be composed of thousands of related websites, and operators take steps to disguise their identities. Officials also face challenges investigating and prosecuting operators because they are often located abroad in countries that are unable or unwilling to aid U.S. agencies.⁸²

Many federal agencies play a role in investigating illegal Internet pharmacies, including the Federal Bureau of Investigation ("FBI"), U.S. Immigration and Customs Enforcement ("ICE"), Customs and Border Protection ("CBP"), the U.S. Postal Inspection Service ("USPIS"), and the Internal Revenue Service ("IRS"). This article focuses on the enforcement efforts of four federal agencies: the FDA, the DEA, the Department of Justice ("DOJ"), and CBP.

Food and Drug Administration

To ensure that drugs are safe and effective as required under the FDCA, the FDA takes action against Internet pharmacies that sell unapproved, misbranded, and/or adulterated drugs. The FDA's Office of Criminal Investigations ("FDA-OCI") spearheads many of the FDA's enforcement efforts and often works in conjunction with the DOJ to prosecute criminal actors.

Since 2011, the FDA has issued over 55 warning letters to Internet pharmacy network operators, who run thousands of illegal Internet

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pharmacy Web sites.⁸³ For example, in 2013, the FDA sent a warning letter to EvaPharmacy, a rogue pharmacy network that the FDA tied to over 300 illegal Web sites. The FDA noted that EvaPharmacy sold “Levitra Super Force” and “Viagra Super Force,” unapproved drugs that contain (in part) the names of approved U.S. drugs (Levitra and Viagra, respectively). In addition to selling unapproved drugs, EvaPharmacy sold prescription drugs without requiring a prescription, which rendered the drugs misbranded under the FDCA. When the FDA issues warning letters to Internet pharmacy networks, it also sends copies of these letters to the governments of the countries from which the Web sites operate, if known.⁸⁴ According to the FDA, approximately 30 percent of Internet pharmacy Web sites that receive warning letters stop their illegal activity.⁸⁵

The FDA also works with the DOJ, DEA, and other federal and state agencies to prosecute operators of illegal Internet pharmacies. For example, in 2017 the FDA-OCI and the DOJ announced the sentencing of two Louisiana residents for fraud conspiracy, wire fraud, mail fraud, and money laundering in connection with the operation of illegal Internet pharmacies. The press release acknowledged the assistance of ICE, the FBI, and the IRS.⁸⁶ According to a GAO report, in the two-year period between 2010 and 2012, the FDA initiated 227 rogue Internet pharmacy investigations, which led to the conviction of 219 individuals.⁸⁷

The FDA also investigates Internet pharmacies that sell misbranded, adulterated, and counterfeit drugs directly to U.S. physicians.⁸⁸ In the CanadaDrugs.com case, the FDA-OCI and the DOJ worked together to indict the operators of CanadaDrugs.com and its wholesale affiliates, who sold \$78 million worth of counterfeit

cancer drugs to U.S. physicians and practice groups.

The FDA additionally works with the CBP and USPIS to screen packages suspected of containing illegal drugs. In light of the opioid epidemic, the FDA commissioner in 2018 pushed to double the number of international packages reviewed annually by FDA inspectors.⁸⁹

Drug Enforcement Administration

The DEA investigates violations of the Ryan Haight Act, which, in addition to requiring a valid prescription, requires any entity that sells, or facilitates the sale, of controlled substances by means of the Internet to obtain a modification of its DEA pharmacy registration that expressly authorizes such online activity.⁹⁰ To be eligible for this modified registration, pharmacies must be authorized to dispense controlled substances under applicable state law; therefore, pharmacies based in foreign countries are not eligible.⁹¹ To the best of the authors' knowledge, the DEA has not yet approved any modified registrations for online sales.

Between 2010 and 2012, the DEA conducted 49 investigations into illegal Internet pharmacies.⁹² A couple of more recent examples: in 2016, the DEA worked with the DOJ, FDA, and USPIS to bring charges against Maurice Malin, a New York pharmacist who sold over five million prescription Butalbital pills to U.S. consumers who had filled out online questionnaires to obtain the drugs.⁹³ Butalbital, a barbiturate, is a Schedule III controlled substance. In 2017, Mr. Malin pled guilty to the charges.⁹⁴ In another case, Skyler Prael, an Illinois resident, pled guilty in 2017 to importing tramadol powder from overseas and using an encapsulating machine to create tramadol capsules. Prael then sold over 80,000 units of tramadol online to U.S. consumers without requiring a valid prescription.⁹⁵

Tramadol is a Schedule IV controlled substance and a synthetic opioid.

Department of Justice

The DOJ works in conjunction with the FDA, DEA, and other federal agencies to investigate and prosecute illegal Internet pharmacy operators. For example, in late 2016 two Florida men pled guilty to crimes including conspiracy, distribution of controlled substances, and money laundering. These individuals operated multiple Internet pharmacy Web sites and sold prescription drugs, including controlled substances, without requiring a prescription. The case involved cooperation among the DOJ, FDA, DEA, IRS, USPIS, state and local police departments, as well as the Florida Department of Health.⁹⁶

The DOJ also investigates companies that facilitate the unlawful distribution of prescription drugs. In 2011, the DOJ and the FDA-OCI worked together to investigate Google for improperly assisting Canadian Internet pharmacy advertisers to run advertisements that targeted the United States, which resulted in the unlawful importation of controlled and non-controlled prescription drugs into the United States. Ultimately, Google agreed to: (1) forfeit \$500 million generated by online ads and prescription drug sales; and (2) adopt compliance and reporting measures to ensure future compliance.⁹⁷

The DOJ also worked with the FDA-OCI, the DEA, and the North Carolina Board of Pharmacy to investigate the use of the United Parcel Service (“UPS”) by illegal Internet pharmacies. In 2013, UPS agreed to forfeit \$40 million in payments from illegal Internet pharmacies and to implement a compliance program to prevent future use of UPS's services to ship illegal drugs.⁹⁸ A similar case was brought against FedEx;⁹⁹ however, the DOJ dropped the case several days into the trial.¹⁰⁰

To help stem the tide of Internet-based opioid sales, the DOJ has increased its efforts to prosecute individuals involved in the online sale of controlled substances. In January 2018 the U.S. Attorney General announced the creation of the Joint Criminal Opioid Darknet Enforcement (“J-CODE”) team, a DOJ and FBI task force that focuses on shutting down online drug marketplaces.¹⁰¹ As of April 2019, J-CODE announced the completion of Operations Disarray and SaboTor.¹⁰² Collectively, these operations resulted in the arrests of 69 suspects.¹⁰³ As part of Operation SaboTor, U.S. and international law enforcement agencies shut down 50 Darknet accounts used for illegal activity and seized 299.5 kilograms of drugs, 51 firearms, and more than \$7 million.¹⁰⁴

Customs and Border Patrol

Preventing drugs from being shipped into the United States is part of the CBP’s mandate. In early 2018, the Senate Permanent Subcommittee on Investigations issued a report identifying vulnerabilities in the international mail system, which it connected to the opioid epidemic.¹⁰⁵ Later that year, the U.S. Postal Service’s (“USPS”) Office of Inspector General studied the shipping practices of illicit online drug sellers and determined that, in cases where the sellers reported a preferred shipping method, most claimed to use the USPS.¹⁰⁶

In response to these reports and as part of a sweeping legislative package aimed at stemming the opioid crisis, Congress passed the Synthetics Trafficking and Overdose Prevention Act (“STOP Act”) in late 2018.¹⁰⁷ It was quickly signed into law. The STOP Act requires that the USPS collect “advance electronic data” (“AED”) on the vast majority of packages entering the United States.¹⁰⁸ This aids the CBP’s and USPS’s ability to target packages containing illegal drugs. The STOP Act set compliance deadlines: by the end of 2018, the USPS was required to collect AED on 100

percent of packages from China and 70 percent of packages in the aggregate. According to the Trump administration, since the enactment of the STOP Act CBP has stopped over six times more packages containing fentanyl.¹⁰⁹ Despite these claims, some sources question whether the deadlines set by the STOP Act have been met.¹¹⁰ The Secretary of Homeland Security and the Postmaster General were required to submit a report to Congress in April 2019. This deadline was not met.

State Enforcement

State medical and pharmacy boards discipline physicians, pharmacies, and pharmacists who fail to meet state licensure and professional conduct requirements. In so doing, they play a major role in halting U.S.-based illegal Internet pharmacies.

State medical boards have reprimanded, suspended, and even revoked licensure where physicians have prescribed outside a proper physician-patient relationship. Typically, violators are found to have engaged in “unprofessional conduct,” as that term is defined under state law. For example, the Rhode Island Board of Medical License and Discipline reprimanded a physician who entered into an agreement with Rx-Partners, a major illegal Internet pharmacy network. The physician had agreed to write prescriptions for individuals based on responses given via online questionnaires; the prescriptions were then filled by speedyrxdrugs.com. The Rhode Island authorities concluded that the physician had engaged in unprofessional conduct by writing prescriptions when a doctor-patient relationship had not been established.¹¹¹ In New York, a physician’s license was revoked after she issued 75,000 prescriptions based on “limited and grossly insufficient” information provided in online questionnaires.¹¹²

State pharmacy regulators have taken similar action against pharmacies that have acted as “fulfillment centers” for illegal Internet drug

sellers; they have also disciplined participating pharmacists for unprofessional conduct.¹¹³ Occasionally, state boards of pharmacy go so far as to shut down pharmacies engaged in dispensing prescription drugs illegally via the Internet. For example, the Kansas State Board of Pharmacy issued a cease-and-desist order to Hogan’s Pharmacy, finding that it posed an immediate danger to the public because it had dispensed thousands of addictive drugs that had been prescribed pursuant to online questionnaires, which resulted in the death of at least one individual.¹¹⁴

International Approaches

Because illegal Internet pharmacy networks often operate from outside of the United States, international cooperation is key to successful prosecution. In an example provided by the GAO, one illegal Internet pharmacy registered its domain name in Russia, used Web site servers located in China and Brazil, processed payments through an Azerbaijani bank, and shipped drugs from India.¹¹⁵ Unfortunately, many illegal Internet pharmacies operate in jurisdictions that do not cooperate with U.S. law enforcement.

For the last 10 years, the International Criminal Police Organization (“INTERPOL”), which includes 194 member countries, has overseen “Operation Pangea,” a week-long international enforcement effort aimed at tackling illegal online medicine and medical device sales.¹¹⁶ In 2018, 116 countries participated, 10 million illicit and counterfeit medicines were seized, and 3,671 Web sites were taken offline.¹¹⁷

In recent years, governments and stakeholders have pushed for additional international cooperation in this area. One notable effort: On January 1, 2016, the Council of Europe’s MEDICRIME Convention came into force. The MEDICRIME Convention is a treaty that criminalizes trafficking in counterfeit medicine, including

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trafficking via the Internet. It also lays down a framework for (1) national and international cooperation among the health, police, and customs authorities; (2) measures for crime prevention that involve the private sector; and (3) the effective prosecution of crime and the protection of victims and witnesses.¹¹⁸

There are also some important international efforts aimed at protecting foreign consumers from illegal Internet pharmacies. Most notably, in 2015 the European Union (“EU”) introduced the “common logo” as part of its Falsified Medicines Directive.¹¹⁹ All legitimate Internet pharmacies operating in EU member states must display the “common logo” on their Web sites. To verify a pharmacy’s legal compliance, a consumer can click on the logo and is then redirected to the applicable government’s verification Web page. Each EU member state keeps an updated list of verified legitimate pharmacies. However, the EU common logo does not indicate EU-wide legality, because the EU has not harmonized regulations regarding the retail supply of medicines. Therefore, a medicine may be sold over the counter in one jurisdiction but require a prescription in another.

Private Sector Efforts

In response to government action and in an effort to protect U.S. consumers, Internet intermediaries have implemented voluntary measures to block illegal online drug sellers and to educate consumers about the dangers associated with illicit Internet pharmacies. Many domain name registrars, including GoDaddy, Rightside, and Realtime Register, terminate service and lock domain names where they have been used to sell prescription drugs illegally.¹²⁰ Others have recently stepped up, as well. In March 2019 Neustar, the company that administers the .us top level domain

on behalf of the Department of Commerce, announced it will increase enforcement of those who violate its existing ban on the sale or distribution of illegal opioids.¹²¹ In April 2019 the FDA and the Department of Commerce’s National Telecommunications and Information Administration (“NTIA”) announced that they “are working with other key entities that have a role in the registration of domain names, including Verisign, which oversees .com, and Public Interest Registry, which manages .org, on a framework focused on reducing the availability of opioids illegally offered for sale online. It also will help increase transparency and accountability in the domain name system and inform future conversations about ‘trusted notifier’ programs expected to take place at the Internet Corporation for Assigned Names and Numbers (ICANN).”¹²²

Internet advertising platforms, including Google, Bing, Snapchat, and Twitter require NABP verification for Internet pharmacy advertising. Credit card brands (e.g., Visa and MasterCard) and payment processors also require NABP or similar certification. Visa, in collaboration with LegitScript, has even published an Online Pharmacy Guide for Acquirers to ensure that its member banks comply with applicable law and Visa policies.¹²³ Shipping companies, including UPS and FedEx, have implemented compliance programs designed to ensure that illegal Internet pharmacies will not be able to use their services to distribute drugs.

Stakeholders have also formed coalitions, including ASOP Global, the Center for Safe Internet Pharmacies, Fight the Fakes, the European Alliance for Access to Safe Medicines, and the Partnership for Safe Medicines.¹²⁴ These organizations work to promote access to safe medicines and to push for government and

voluntary solutions to the problems of illegal online drug sellers.¹²⁵

Next Steps

Despite government and private sector efforts, significant gaps exist that allow the continued success of illegal online drug sales. Three in particular stand out: domain name registration, international shipping, and organic Internet search results.

Domain name registrars provide domain name registration services to companies or individuals that would like to operate a specific Web address. These registrars are accredited by ICANN, which, as of 2013, contractually requires them to “investigate and respond appropriately to any reports of abuse.”¹²⁶ As discussed above, many domain name registrars take prompt action to investigate and lock illegal Internet pharmacy domain names, thereby preventing these domain names from future illegal use. Others, however, have failed to implement adequate anti-abuse policies and are well-known “safe havens” for illegal Internet pharmacies. Although there are over 2,500 accredited domain name registrars, some reports indicate that 40 percent of identified illegal Internet pharmacies are registered with the same 10 registrars.¹²⁷ To date, ICANN has failed to take significant action regarding these noncompliant registrars.

Collecting AED is not the only way to stop the shipment of illegal drugs. The Senate Permanent Subcommittee on Investigations has pushed for the USPS, CBP, and private shipping companies (e.g., FedEx, UPS, DHL) to share information about best practices and known shippers of illegal items. It has also suggested that peer-to-peer payment platforms, including Western Union, MoneyGram, and PayPal participate in information sharing.

Government officials are additionally calling on Internet search engines and social media platforms to do more to protect consumers from illegal online drug sellers. Internet search engines continue to include Web sites that openly sell illegal drugs, including fentanyl and other deadly opioids, in their organic search results. In the Senate Permanent Subcommittee on Investigations report, referenced above, investigators noted that “simple Internet searches for ‘fentanyl for sale’ identified Web sites openly advertising synthetic opioids for purchase.”¹²⁸

In early 2018, a group of senators wrote to Google, Microsoft, Yahoo!, and Pinterest expressing concern about the role that these companies play in facilitating the sale of opioids. While acknowledging that these companies have compliance policies in place regarding Internet pharmacies, the senators urged these companies to take the following additional steps to stem the tide in the opioid crisis:

- Directing users to legal and legitimate pharmacies that require a valid prescription as a condition of sale when users search for medicines on each platforms [sic];
- Disabling the ability to search for illicit drugs through each platform;
- Requiring each platform to report to law enforcement when that platform receives information indicating that a company wants to advertise the use of or sale of illicit narcotics;
- Establishing a 24/7 telephone point of contact with whom law enforcement can communicate directly; and
- Incorporating training for each platform’s security reviewers to enable them to better recognize these threats when they first arise.¹²⁹

By disabling the ability to search for illegal online drug sellers, Internet search engines and social media platforms would deny these criminal

actors the visibility they need to be successful.

Responding to congressional calls to do more to address the growing problem of illegal online drug sales, Bing recently added pop-up warnings for Web sites that are on NABP’s “Not Recommended List.” According to the NABP, the “Not Recommended List” includes those Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards.¹³⁰

As government and the private sector work together to stop illegal online drug sellers, these criminal actors find new and effective ways to reach consumers. In fact, mobile apps appear to be the new frontier for illegal Internet pharmacies. While government works to fill regulatory gaps, the private sector must recognize the dangers presented by illegal online drug sales and take proactive steps to protect the public.

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Chair's Corner

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and groupthink. Creating and nurturing a culture of diversity and inclusion requires us to reach out, empathize with, and include individuals who may come from very different backgrounds from ours. It requires cross-cultural competency, maturity, and a worldview characterized by a willingness to challenge deep-seated assumptions we may have regarding others' values, belief systems, and cultures. Perhaps most importantly though, creating a culture of diversity and inclusion requires that we strive to nurture a sense of **belonging** in those who work, live, play, and worship alongside us, in our shared spaces and communities. Belongingness represents – and gives power and force – to the concepts of diversity and inclusion. Belongingness means acceptance. It means feeling like you fit in, as if you have a contribution to make. Belongingness is a mindset characterized by being able to be authentic, knowing I matter, and that my voice is essential.

The concept of belongingness goes beyond diversity and inclusion. Diversity is being invited to the party, inclusion is being asked to dance, and belongingness is being able to dance like no one is watching. Belongingness is an innate sense of psychological and emotional security that allows people to be their authentic selves and contribute in their own, unique way.

The Marvel Comics movie, *Black Panther*, provides an analogy of this concept of belongingness. And, as a Marvel Comics fan, this analogy particularly resonates with me. The movie was a box office smash and **the** highest grossing film of 2018. Among African-Americans, the movie itself was a movement. There were efforts across the nation to get as many children of color in as many theaters as possible to see the movie, and for many of us, the movie was a significant cultural moment.

I think about it this way: Marvel movies have been diverse. They have had black actors, black extras, and certainly, there were black people working behind the scenes. That might be considered diversity. And, we've seen inclusivity in Marvel movies. Don Cheadle played "Rhodey" in *Iron Man 2*. He was a super hero in his own right, a feature character who fought alongside Robert Downey Jr.'s Ironman character. But *Black Panther* truly epitomized the spirit of representation. It gave those of us who are African-American fans of Marvel movies a sense of belongingness that had not really been there before.

This is because belongingness must also be about representation. It is about being seen, but also about seeing yourself reflected at the very highest positions in an organization, in leadership roles, and at the table where decisions

are being made. What we see becomes a part of our memory and our existence. This shapes the way we see the world, ourselves, and others. Whether it is on the movie screen, in the legal profession, in the ABA, or in the HLS, people are more likely to be engaged, committed, and productive when we they can identify with those who have succeeded and visualize ourselves doing the same. As my mother says, "If you can see it, you can be it."

From the moment I became a member of the ABA HLS, in 2004, I was made to feel as if I belonged. Members of the section, like Hal Katz, Bill Horton, David Johnson, Greg Pemberton, Priscilla Keith – and many more – welcomed and supported my authentic self. They took practical steps to make sure I felt like I belonged. They introduced me to the other members, sought my opinion, solicited my input, and helped me carve out a role for myself in the HLS as a leader. This sense of belongingness gave me the confidence to work with HLS leaders to help create the Public Health and Policy Interest Group, and to establish a first of its kind partnership and Memorandum of Understanding between the ABA and the Centers for Disease Control and Prevention.

This culture of belongingness has also made it easy for me to introduce the HLS to students and public health lawyers that I work with who are looking for community. I am confident that when I bring someone to the HLS, they will be welcomed and supported, regardless of their age, race, ethnicity, or sexual identity.

Belongingness must be about giving those who have traditionally been on the sidelines their time in the sun, and a chance to maximize their inherent human potential and capacities for the collective good. When we see those with whom we share an identity achieving great things, we too feel empowered. And, although we can always do better, I am proud and impressed with the commitment the ABA and the HLS has to fostering diversity, inclusion, and belongingness.

I recently saw a quote that really highlights what belongingness looks like. The language is from a sign that hangs in a high school, and focuses on students. For the purposes of this column, I replaced "school" with "section."

"You are a member of a [section] where we not only respect differences, we embrace our diversity. We embrace one another's race and ethnicity. We embrace one another's family background, heritage, language, culture. We embrace one another's religion and your right to your own personal customs and beliefs. We embrace your sexual orientation and your

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gender identity. We embrace your special needs. We embrace **you...** And value you as individual human beings. Never forget: you belong here in the [Health Law Section] – each and every one of you.”

I think that sums it up nicely.

* * *

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* The findings and conclusions in this article are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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EMPLOYMENT-BASED LEGAL AND POLICY SOLUTIONS FOR FEMALE VICTIMS OF INTIMATE PARTNER VIOLENCE

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Introduction

The Centers for Disease Control & Prevention (“CDC”) defines “intimate partner violence” (“IPV”) as the physical violence, sexual violence, stalking and psychological aggression by a current or former intimate partner such as a spouse or a boyfriend/girlfriend.¹ IPV continues to be a prevalent public health problem, despite laws such as the 1994 Violence Against Women Act (“VAWA”). IPV can happen to both men and women, though it occurs more prevalently to women. According to the National Coalition Against Domestic Violence (“NCADV”), one in four women and one in nine men experience severe intimate partner violence, intimate partner contact sexual violence, and/or intimate partner stalking.² The CDC-sponsored National Intimate Partner & Sexual Violence Survey (“NISVS”) reported similar numbers.³ That survey found that one in four women (27.4 percent) have experienced contact sexual violence,⁴ physical violence and/or stalking by an intimate partner and reported an IPV-related impact.⁵ State estimates of IPV against women ranged from 19.7 percent to 35.3 percent.⁶

IPV is an important public health problem because of its effects on women’s mental and physical health, on women’s ability to succeed within society, and on children of IPV victims, as well as the costs to society as a whole. The lifetime economic costs of IPV in the United States is \$3.6 trillion.⁷ Of this amount, 59 percent

is attributed to medical costs, 37 percent is attributed to lost productivity, two percent is attributed to criminal justice costs, and two percent is attributed to other various costs, such as victim property loss or damage.⁸

IPV needs to be addressed by law and policy changes at both the state and federal level. Economic dependence is frequently cited as one of the most significant barriers to seeking help or leaving an abusive relationship.⁹ Recent legal developments have also highlighted the importance of employment-related solutions for IPV. Therefore, changes should be focused on providing IPV victims with employment stability in order to help them overcome this economic dependence barrier and seek help and/or leave their abuser.

This article lays out employment-based recommendations for alleviating the consequences of IPV in the United States. It defines the extent of the problem and details the physical, mental, economic, and societal consequences of IPV. The article discusses the relevant laws at both the state and federal level and includes a 10-state survey of laws related to IPV. The article then analyzes four legal and/or policy recommendations to address this issue. The first recommendation suggests an amendment to state laws and the Family and Medical Leave Act (“FMLA”) to provide for paid medical leave for victims of IPV. The second recommendation considers how the Patient Protection and Affordable Care Act (“PPACA”) can be amended to require greater coverage of screening and counseling for victims. The third recommendation looks at how Title VII of the Civil Rights Act (“Title VII”) could be used to offer protections against discrimination and retaliation of

employees who are victims of IPV. The fourth recommendation looks at how community-based state programs funded by VAWA and state initiatives could assist unemployed victims with securing employment.

IPV as a Public Health Problem

IPV is complicated and multi-faceted, warranting problem-solving across all disciplines, including but not limited to medicine, law, psychology, and sociology. The World Health Organization’s study on social determinants and sexual and reproductive health explores factors associated with sexual violence and looks at the problem of sexual violence on four levels: individual, relationship, community, and society.¹⁰ Factors that impact IPV at the individual level are age (particularly marriage age), drug use, poverty level, history of abuse as a child, and history of sex work.¹¹ Factors that impact IPV at the relationship level are age differences between partners, barriers to discussion/negotiations about sex, and male dominance in the family.¹² Factors that impact IPV at the community level are the lack of community sanctions against sexual violence and community norms that discourage women’s sexual autonomy.¹³ Finally, factors that impact IPV at the society level are the lack of criminal sanctions against sexual violence, weak laws and policies related to the civil rights of women, and high levels of violence in the society – including armed conflict.¹⁴ This multi-level approach is important to keep in mind when analyzing policy solutions for IPV.

While IPV can happen to anyone, IPV is more likely to occur among particular groups. Data indicates that

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Employment-Based Legal and Policy Solutions for Female Victims

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non-Hispanic black women, American Indian or Alaskan Native women, and multi-racial non-Hispanic women are most likely to be victims of intimate partner violence.¹⁵ National data from the CDC's NISVS found that 45.1 percent of African American women, 47.5 percent of Indian American women, and 56.6 percent of multiracial women have experienced contact sexual violence, physical violence, and/or stalking by an intimate partner within their lifetime.¹⁶ This is high compared to the prevalence in the population of white women, of which 37.3 percent have experienced IPV.¹⁷ IPV and poverty are intertwined as well, although studies have been inconclusive on the exact relationship between the two. Some data has shown that poverty is a contributing factor for IPV.¹⁸ Other data has indicated that poverty is just higher in low-income populations, and is not actually a contributing factor for IPV.¹⁹ One study found that physical IPV, not emotional IPV is associated with low-income populations.²⁰

IPV is a clear public health problem, with both immediate and long-term physical and mental health effects. Such IPV-related health impacts include feeling fearful, being concerned for one's safety, and experiencing symptoms of post-traumatic stress disorder ("PTSD").²¹ According to the NISVS, 51.8 percent of female lifetime victims²² of IPV experienced symptoms of PTSD, 56.6 percent felt concerned for their safety, and 61.9 percent felt fearful.²³ Long-term physical effects include chronic pain, chronic headaches, high blood pressure, difficulty sleeping, poor mental health, and activity limitations.²⁴

IPV can have non-health related consequences, as well. One study found that domestic violence leads to substantially diminished work hours for women.²⁵ The study found that domestic violence can result in a

reduction of up to 137 work hours annually of an average woman in the study's three-year sample.²⁶ As a result, women experiencing IPV may be less likely to obtain and retain stable employment.²⁷ Another study found that experiencing IPV predicted less stable employment over a three-year period, indicating a potential long-term impact of IPV on employment stability.²⁸

As a result of such employment instability, victims of IPV may be forced to be dependent upon their spouse/partner for financial support. As stated earlier, economic dependence on an abusive intimate partner is frequently cited as one of the most significant barriers to seeking help or leaving an abusive relationship.²⁹

Relevant Laws

Both state and federal laws play distinct roles in addressing the issue of IPV. There are currently no federal laws specifically offering employment or other protections to victims of IPV. The relevant federal laws are the FMLA, PPACA, Title VII, and VAWA. The first three of these federal laws were chosen for the purpose of this article because each of these laws has the potential to provide some type of employment benefit or protection for victims of IPV, while VAWA was chosen because it authorizes funding for community-based efforts to reduce and improve issues related to IPV. The relevant state laws are those that fill the gaps left by the federal laws discussed above. They do so by offering increased protections for victims, and should be used by lawmakers as a guide for amending the federal laws.

It is important to note that recent developments impact two of the laws that will be discussed in this article. The first is the December 2018 United States District Court for

the Northern District of Texas ruling that struck down the constitutionality of PPACA.³⁰ The second is the government shutdown from December 22, 2018 to January 25, 2019,³¹ which caused VAWA to expire.³²

Federal Laws

FMLA

Enacted in 1993, the FMLA is a requirement placed upon employers to allow leave for an employee due to family-related events. The FMLA entitles an "eligible employee" to 12 workweeks of leave during any 12-month period for one or more of the following: (1) the birth of a son or daughter of the employee and in order to care for such son or daughter; (2) the placement of a son or daughter with the employee for adoption or foster care; (3) to care for the spouse, or a son, daughter, or parent, of the employee, if such spouse, son, daughter, or parent has a serious health condition; (4) a serious health condition that makes the employee unable to perform the functions of the position of such employee; or (5) because of any qualifying exigency (as the Secretary shall, by regulation, determine) arising out of the fact that the spouse, or a son, daughter, or parent of the employee is on covered active duty (or has been notified of an impending call or order to covered active duty) in the Armed Forces.³³ An employee who takes leave under the FMLA is entitled to both the same employment position and the employment benefits that he/she had when he/she took leave.³⁴ The taking of leave shall not result in the loss of any employment benefit accrued prior to the date on which leave commenced.³⁵

Under the FMLA, "eligible employee" means an employee who has been employed for at least 12 months by the employer with respect to whom leave is requested, and for at least 1,250 hours of service with such

employer during the previous 12-month period.³⁶ The requirements of the FMLA apply to employers who employ 50 or more employees for 20 or more calendar workweeks in the current or preceding year.³⁷

A “serious health condition” under the FMLA means an illness, injury, impairment, or physical or mental condition that involves inpatient care in a hospital, hospice, or residential medical care facility, or continuing treatment by a healthcare provider.³⁸ Under § 2613 of the FMLA, an employee must provide certain information in order to certify that his/her health condition meets these requirements. Certification is sufficient for showing a serious health condition if the employee provides the following to his/her employer:

1. the date on which the serious health condition commenced;
2. the probable duration of the condition; and
3. a statement that the employee is unable to perform the functions of the position of the employee.³⁹

Under the FMLA, a health condition is only a “serious health condition” allowing for leave if the condition involved treatment at a healthcare facility or by a healthcare provider. Therefore, a victim of IPV who has health conditions resulting from his/her abuse would only be able to take FMLA leave if he/she received treatment for the condition. If a victim has not received treatment for his/her health condition, he/she will not be able to receive leave. As a result of not receiving FMLA leave, he/she may have to utilize other avenues in order to get time off work to recover from any serious mental or physical condition resulting from the abuse. He/she may have to take more time off than he/she is allotted per year, which could result in adverse employment action and eventual termination. If he/she is terminated and loses his/her source of income, he/she may have to be dependent upon the

abusive spouse/partner for support until he/she can find another source of income. As stated earlier, such economic dependence upon the abusive spouse/partner prevents victims from seeking help and getting out of abusive situations.⁴⁰

Overall, the FMLA doesn’t do enough to protect victims of IPV who may not qualify for leave under the statute. Some jurisdictions have enacted laws to fill the gaps that the FMLA leaves for victims, as described below.⁴¹ The FMLA and state gap-filling laws can be amended to offer more protections for victims who may need work leave due to health conditions resulting from IPV.

PPACA

Enacted in 2010, PPACA brought forth a wave of changes to the United States healthcare system. Overall, PPACA sought to improve access and increase utilization of preventive care services. Some of the changes that PPACA implemented include the following: (1) expanding Medicaid access to cover all adults with an income below 138 percent of the federal poverty level (“FPL”);⁴² (2) improving health insurance plans by requiring employer-based health insurance and state programs that opt to expand Medicaid to include 10 essential health benefits, and (3) prohibiting health insurance companies from setting plan coverage and amounts based upon pre-existing conditions.⁴³ The implementation of these PPACA provisions are now in question due to the recent Texas case striking down the constitutionality of PPACA.⁴⁴

Women’s preventive health services are included as part of the essential health benefits mandated by PPACA.⁴⁵ The Health Resources and Services Administration (“HRSA”) developed the Women’s Preventive Services Guidelines in order to specify the healthcare services that PPACA requires. Under these guidelines, screening and counseling for interpersonal and domestic violence

is required.⁴⁶ Under the screening requirement, once the patient reports that she is experiencing IPV, the physician need only refer her to local domestic violence support agencies.⁴⁷ Additionally, the requirements for both screening and counseling for victims of domestic violence do not specify how frequently such services must be provided.⁴⁸

While PPACA is not an employment related law, improving the health of women affected by IPV arguably would help them to obtain or maintain employment. These requirements for women’s preventive health services are a great leap forward compared to the coverage that was in place previously. However, they still don’t do enough for victims of IPV. First, the requirement only provides for basic information exchange between the counselor and patient, and referrals to local domestic violence support agencies when the patient reports abuse. Second, since there are no specific frequency requirements, screening and counseling may not be provided as often as needed. Therefore the coverage requirements for screening and counseling for victims of IPV are inadequate under the current version of PPACA because the requirements do not require referrals to healthcare professionals who are able to treat victims of IPV for the mental and physical health effects that result from their abuse.

Title VII

Title VII provides employment discrimination protections for certain groups. The statute states that it is an unlawful employment practice for an employer to fail or refuse to refer for employment, or otherwise to discriminate against, any individual because of his/her race, color, religion, sex, or national origin, or to classify or refer for employment any individual on the basis of race, color, religion, sex, or national origin.⁴⁹ The Equal Employment Opportunity Commission (“EEOC”)

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is responsible for enforcing Title VII and thus has the authority to investigate charges of discrimination against an employer.⁵⁰

There have been cases in which an employee has sued her employer for discrimination due to her status as a domestic violence victim. In *Hillware v. Snyder*, the plaintiff claimed that she was denied work with the National Football League (“NFL”) because she is African American, female, and a victim of domestic violence.⁵¹ She was previously employed by the NFL, and at an unspecified time she became a victim of domestic violence and was forced to flee for the safety of her children.⁵² Upon discovering “Plaintiff’s personal emotional cries for help,” hiring officials with the NFL and the team she had worked for allegedly “shun[ned] Plaintiff for more than 9, nearly 10 years,” and they were “non-responsive to [Plaintiff’s] numerous job application submissions” for marketing, sales, and business development positions.⁵³ She sued under Title VII, the Age Discrimination in Employment Act (“ADEA”), and the Americans with Disabilities Act (“ADA”).⁵⁴ She lost on a failure to exhaust administrative remedies.⁵⁵

Additionally, in *Lane v. Forever of PA, Inc.*, the plaintiff alleged that the defendant fired her because of her status as a victim of domestic violence.⁵⁶ She argued that her termination because of her status as a victim of domestic violence disparately impacts women in violation of Title VII.⁵⁷ The U.S. District Court for the Western District of Pennsylvania held that since the plaintiff was an at-will employee, she did not have a claim against the employer because there is no exception to the broadly construed at-will employment doctrine.⁵⁸

Considering that there have been cases in which a female plaintiff has sued under Title VII because of her status as a victim of domestic

violence, Title VII could potentially be interpreted or amended to provide certain protections for victims of IPV. The role of Title VII in providing such protections will be discussed below.

VAWA

Enacted in 1993 and codified at 34 U.S.C. § 12291 to § 12512, VAWA was part of the Violent Crime Control and Law Enforcement Act. Under VAWA, “domestic violence” is defined as any felony or misdemeanor crimes of violence committed by a current or former spouse or intimate partner of the victim, by: (1) a person with whom the victim shares a child in common; (2) a person who is cohabitating with or has cohabitated with the victim as a spouse or intimate partner; (3) a person similarly situated to a spouse of the victim under the domestic or family violence laws of the jurisdiction receiving grant monies; or (4) any other person against an adult or youth victim who is protected from that person’s acts under the domestic or family violence laws of the jurisdiction.⁵⁹

In addition to enhanced investigation and prosecution of domestic violence offenders, VAWA provides for funding authorizations for what it called a “domestic violence task force.” VAWA states that the Attorney General, in consultation with national nonprofit, nongovernmental organizations whose primary expertise is in domestic violence, shall establish a task force to coordinate research on domestic violence and to report to Congress on any overlapping or duplication of efforts on domestic violence issues.⁶⁰ Funds appropriated under this section shall be used to develop a coordinated strategy to strengthen research focused on domestic violence education, prevention, and intervention strategies.⁶¹ VAWA also provides funding for a sexual assault state and tribal coalition.⁶² The funding

authorizations that VAWA grants can be used to support community-based programs aimed at assisting victims with obtaining employment. These programs are discussed in more detail below.

State Gap-Filling Laws

States and municipalities play a crucial role in solving public health problems because their laws can fill in gaps otherwise left by federal laws. The 10-jurisdiction survey below⁶³ lists several state laws that offer the following two protections: (1) allow work leave related to domestic violence; and (2) protect IPV victims from employment discrimination and retaliation. Many of the laws that offer these protections have been passed in the last five years. Seven out of the ten laws surveyed require employers to allow work leave for victims of domestic violence. Out of the ten that were surveyed, seven protect victims of domestic violence from retaliatory or discriminatory actions by employers. States have been slow to enact these types of laws because states do not view IPV as a pervasive public health problem.⁶⁴ Thus, it is important to note that these laws were passed after legislators considered statistics on the adverse impact of domestic violence in their particular state.

In the Table of the survey, the protection entitled “Allow work leave related to IPV?,” refers to state or municipal laws that fill gaps left by the FMLA. The statutes fall into two broad categories, reflected in the language of the law. Some of the laws offer an entitlement to work leave, while others prohibit an employer from penalizing an employee for taking time off due to domestic violence. The effect of these two types of law is essentially the same, as both allow for some type of leave. However, the administrative steps that must be completed by an employee taking leave may vary. Six states offer this

type of protection. For example, California’s law does not offer leave, but rather prohibits adverse employment action by the employer against an employee who takes leave. It states the following:

An employer shall not discharge or in any manner discriminate or retaliate against an employee who is a victim of domestic violence, sexual assault, or stalking for taking time off from work to obtain or attempt to obtain any relief, including, but not limited to, a temporary restraining order, restraining order, or other injunctive relief, to help ensure the

health, safety, or welfare of the victim or his or her child.⁶⁵

In contrast, Illinois’ law offers specific entitlement to leave. Section 180/25 of the law states, “an employee who is entitled to take paid or unpaid leave (including family, medical, sick, annual, personal, or similar leave) from employment, pursuant to federal, State, or local law...[m]ay elect to substitute any period of such leave for an equivalent period of leave provided under Section 20.”⁶⁶ The section referred to, § 180/20, states that an employee who is a victim of domestic or sexual violence or an employee who has a family or household

member who is a victim of domestic or sexual violence may take unpaid leave from work if the employee or employee’s family or household member is experiencing an incident of domestic or sexual violence or to address domestic or sexual violence.⁶⁷ Section 180/20’s allotment for leave is the same as the time period offered by the FMLA.⁶⁸

The protection listed in the far-right column of the Table prohibits employers from discriminating or taking retaliatory action against employees because of their status as a victim of IPV. As shown in the Table, the jurisdictions that offer

Table: 10-Jurisdiction Survey: Gap-Filling Laws

JURISDICTION	LAW	EFFECTIVE DATE	ALLOW WORK LEAVE RELATED TO IPV?	PROTECT IPV VICTIMS AGAINST EMPLOYMENT DISCRIMINATION AND RETALIATION?
1. California	West’s Ann.Cal. Labor Code § 230	Jan. 1, 2014	Yes	Yes
2. Florida	West’s F.S.A. § 741.313	Oct. 1, 2013	Yes	Yes
3. Illinois	820 ILCS § 180/20; 820 ILCS § 180/30; 820 ILCS § 180/25	Aug. 24, 2009; Jul. 20, 2015; Jan. 1, 2017	Yes	Yes
4. Maine	26 M.R.S.A. § 850; Domestic Violence Workplace Policy ⁷¹	Oct. 15, 2015	Yes	Yes
5. Massachusetts	Ch. 260: An Act Relative to Domestic Violence ⁷²	Aug. 8, 2014	Yes	Yes
6. Michigan	M.C.L.A. 408.964	Mar. 29, 2019	Yes	No
7. New York	N.Y.C. Admin. Code § 8-107.1 (only New York City)	Aug. 4, 2016	No	Yes
8. North Carolina	None	N/A	No	No
9. Oregon	O.R.S. § 659A.272; O.R.S. § 659A.290	Aug. 2, 2011 (amended)	Yes	Yes
10. Pennsylvania	None	N/A	No	No

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these protections are California, Florida, Illinois, Maine, Massachusetts, New York City, and Oregon. As an example, the law in California provides that an employer shall not discharge or in any manner discriminate or retaliate against an employee because of the employee's status as a victim of domestic violence, sexual assault, or stalking.⁶⁹ States typically model their laws on the language provided in Title VII.⁷⁰

Guide for Lawmakers: Recommendations for Employment-Based and Other Interventions

The following recommendations attempt to mitigate the problem of IPV by treating the symptoms (mental, physical, financial) of IPV, rather than by preventing IPV in itself, because preventing IPV is a larger societal problem that cannot necessarily be solved by changes in law or policy, but rather through changes within society at large.⁷³ The recommendations are offered for two distinct IPV victim populations: those who currently are employed and those who are unemployed. For the population of victims who are currently employed, it is vital that they maintain employment so that they can preserve financial independence. Recommendations for this population of victims are focused on: (1) offering paid work leave for employees who are victims of IPV; (2) protecting and maintaining both public and/or private health insurance for victims of IPV; and (3) offering discrimination and retaliation protections for employees who are victims of IPV.

The recommendations for unemployed victims are focused on developing state and/or federal laws that allocate funding to assist victims with securing employment through two community-based programs. The first

program will use the allocated funding for a professional mentoring program in which female professionals are matched with victims of IPV to guide them through the process of searching, applying, and interviewing for a job. The second program will operate within domestic violence shelters with financial assistance through state subsidies. Shelters will partner with other businesses to provide a multitude of benefits, including free or reduced cost child care, internet and/or computer access, and free or reduced cost gently-used professional clothing. While revising or amending any (or all) of the following laws would be a great step forward in addressing IPV, recent legal developments have changed the landscape, so that the laws with the most promise in effecting change happen to be those that are more employment-related: The federal and state federal medical leave acts and Title VII. Both PPACA and VAWA have run into their own legal issues, making them a less practical avenue.

Enacting State Laws and Changing the FMLA: Paid Leave for Victims

Although the FMLA offers important protections for individuals who need to take time off work for reasons related to family matters or serious health conditions, the FMLA unfortunately does nothing for victims of domestic violence who need to take time off due to their abusive situation. As discussed above, the only reason a victim would be able to take time off work due to IPV would be if she was treated by a healthcare professional for a serious health condition resulting from her abuse. While a victim's health is important, it is not the only factor at issue with respect to this public health problem. Many other factors, such as children, legal proceedings, impoverishment, and housing play a role and must be

considered when changing employment-based policies such as the FMLA. For instance, Illinois' law offering entitlement to leave for victims of domestic violence considers other factors that may warrant leave for victims of domestic violence. ILCS § 180/20 allows victims time off to address domestic violence by:

1. seeking medical attention for, or recovering from, physical or psychological injuries caused by domestic or sexual violence to the employee or the employee's family or household member;
2. obtaining services from a victim services organization for the employee or the employee's family or household member;
3. obtaining psychological or other counseling for the employee or the employee's family or household member;
4. participating in safety planning, temporarily or permanently relocating, or taking other actions to increase the safety of the employee or the employee's family or household member from future domestic or sexual violence or ensure economic security; or
5. seeking legal assistance or remedies to ensure the health and safety of the employee or the employee's family or household member, including preparing for or participating in any civil or criminal legal proceeding related to or derived from domestic or sexual violence.⁷⁴

The FMLA should be amended to allow for more flexible requirements to certify a "serious health condition" under the statute, since some individuals may not have access to care by a healthcare provider or facility. This would allow for paid leave for employees who have suffered adverse mental or physical health conditions due to IPV. As an alternative, federal lawmakers could simply

add a provision to the FMLA specifically for victims of IPV. Lawmakers could also look to state laws, such as the Illinois law, when drafting the language of the new FMLA provision.

State lawmakers should consider Illinois' law and other similar laws when drafting proposed changes and address this issue. The state law should also require that state agencies develop and carry out a method for collecting data on the prevalence and costs associated with IPV in their state. The changes to state laws discussed above were proposed and enacted because of state data regarding IPV, as mentioned in the "purpose" section of these laws. Therefore, there will need to be data in order to inform future policy and/or legal changes to address other issues, such as housing and amending the civil/criminal legal process.

Overall, the FMLA and state-equivalent laws have the potential to keep victims employed during their abuse, because those laws allow for paid leave without the threat of being terminated or losing benefits gained while working. This provides IPV victims with consistent income when they take time off, and job security when they return to work. By retaining income, IPV victims will more likely maintain financial independence, which will allow them the means to support themselves and their children, get help, and leave their abusive intimate partner.

Changing PPACA to Require Coverage of More Frequent Screening and Counseling

Screening and counseling are crucial aspects for improving health outcomes for women who are victims of IPV. Research indicates that screening and counseling for IPV can identify survivors and, in some cases, increase safety, reduce abuse, and improve clinical and social outcomes.⁷⁵ Arguably the more medical support a victim receives would improve her health and enable her to secure or retain

employment. Legislators at the federal level should focus on changing the essential health benefits requirements under PPACA to allow for more thorough and frequent coverage of counseling and screening for victims of IPV.

Policymakers should look to existing screening systems that have been successful. For example, Kaiser Permanente has developed a systems-based approach, which makes use of the entire healthcare environment to improve IPV services.⁷⁶ Its system has been associated with an eightfold increase in IPV identification between 2000 and 2013.⁷⁷ The steps for implementing the Kaiser Permanente approach include, but are not limited to: (1) frequent, brief, focused IPV training; (2) a clear care path for identification and response; and (3) a reliable referral process for on-site behavioral health and to community advocacy services, which have increased clinician confidence and competence in IPV inquiry and intervention.⁷⁸

Changes to screening requirements should provide for consistent screening. A new screening law could state the following:

An employer's health insurance shall cover frequent screening of domestic or intimate partner violence. "Frequent screening" means screening completed every six months for victims of domestic violence. Once a patient reports that he or she is a victim of domestic or intimate partner violence, the treating healthcare provider shall schedule a subsequent screening to occur within six months of the patient's first reporting of his or her abuse.

While PPACA provides coverage for counseling, the frequency requirement is not specified under the guidelines provided by HRSA. Therefore, changes should be aimed at providing for coverage of adequate counseling services for victims of IPV. A change in the law regarding counseling services is going to be more difficult to

implement, given the existing barriers to mental health services in general, which the law has been unable to resolve.⁷⁹

The use of PPACA is further constrained by the precarious nature of its existence, having been declared completely unconstitutional in December 2018. That ruling is currently being appealed, but it is unknown whether and to what extent the law will remain viable.⁸⁰

Title VII and Applicable State Law: IPV Victim Status

Title VII can be amended to offer greater protections for employees who are victims of IPV. As discussed above, employees have used Title VII to sue employers for discriminatory actions due to the employee's status as a victim of IPV, but the plaintiffs were not able to succeed on their claims. States have also passed laws allowing for Title VII-type protections for employees who are victims of IPV. Lawmakers should consider these two developments and amend Title VII accordingly.

Federal lawmakers could look to state law protections and model an amendment to Title VII off a state law, such as California's Labor Code § 230 (quoted above), which offers protections for employees who identify as victims of IPV. Additionally, federal lawmakers could look to the process that took place with respect to the Pregnancy Discrimination Act, which amended Title VII.⁸¹ Pregnant women were often discriminated against in the workplace. The Pregnancy Discrimination Act prohibited such discrimination so that women can retain and obtain steady employment when they are pregnant. The Pregnancy Discrimination Act places discrimination against pregnant women under sex discrimination generally.⁸² To protect female victims of IPV, lawmakers could also place discrimination against female victims of IPV under sex discrimination generally. Lawmakers at the state level should

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consider other states' laws, using the structure and language of those laws as a model for their own laws.

IPV status can also be addressed in state law. Several states have enacted laws modeled after the Americans with Disabilities Act ("ADA") to offer accommodations for employees with IPV victim status.⁸³ For example, to protect IPV victims Illinois and New York City have passed legislation allowing domestic violence victims the right to receive "reasonable accommodations" from their employers so that they may perform their job safely and adequately.⁸⁴ Illinois defines "reasonable accommodation" to include "an adjustment to job structure, workplace facility, or work requirement, including a transfer, reassignment, or modified schedule, leave, a changed telephone number or seating assignment, installation of a lock, or implementation of a safety procedure, in response to actual or threatened domestic or sexual violence."⁸⁵ While these state statutes apply to domestic violence in the workplace, lawmakers could use them as a guide for "reasonable accommodation" for victims who experience IPV outside of the workplace.

Amending Funding Under VAWA: Community-Based Partnerships and Other Programs

Employment provides a multitude of benefits to victims of IPV. The Boston University School of Public Health found that employment is helpful to IPV victims in six ways: (1) improving their finances; (2) promoting physical safety; (3) increasing self-esteem; (4) improving social connectedness; (5) providing mental respite; and (6) providing motivation for a "purpose in life."⁸⁶ The goal of the study was to document specific ways in which work was helpful to IPV victims in order to inform legislation aimed at protecting employment for victims.⁸⁷ In addition to that

study, cross-national evidence indicates that rates of sexual violence are lower in countries where women have higher educational and occupational status.⁸⁸

With this data in mind, changes should be focused on allocating more funding to assist unemployed IPV victims with securing employment. The changes will operate on two levels. The first is a professional mentoring program. The second is various programs and benefits that could be offered by domestic violence shelters, with the help of funding from federal and state subsidies. These two levels would work together to form new state domestic violence coalitions ("SDVCs") focused on employment-based assistance.

At the federal level, funding could come from the Family Violence Prevention Services Act ("FVPSA"), reauthorized in 2010 as part of the Child Abuse Prevention and Treatment Act.⁸⁹ The Child Abuse Prevention and Treatment Act gives the CDC the authority to invest federal funds to support coordinated community responses to address partner violence.⁹⁰ Through the Domestic Prevention Enhancements and Leadership Through Alliances ("DELTA") program,⁹¹ CDC funded fourteen SDVCs.⁹²

At the state level, funding could come from state-allocated funds via VAWA.⁹³ Both the mentoring and assistance programs would be hosted by domestic violence shelters around the United States. The mentoring program would enable currently unemployed IPV victims to connect with mentors within a network of female professionals. The professional mentor would guide the victim through crucial job processes such as interviewing, filling out job applications, and creating a resume. The other community-based program would provide other various services for victims searching for a job. These

services could include but are not limited to child care, the provision of gently-used professional clothing, and assistance with enrollment in federal and state assistance programs. Domestic violence shelters, in utilizing to the full extent the community within the area where the shelter is located, could partner with organizations that already provide child care. Such organizations could be childcare businesses or individuals who provide childcare, who could contract with the domestic violence shelter to provide childcare at a reduced price. In order to compensate these organizations, the state in which the shelter is located could offer tax benefits to businesses or individuals who participate in the program. The shelters could also partner with organizations that offer gently used professional clothing, and the state could offer similar financial incentives for these organizations to participate. Finally, the shelters could assist with enrollment in state and federal assistance programs. The individuals providing assistance could be volunteers who have experience with the enrollment process, or even individuals that the shelter has trained about such enrollment processes. Overall, both of these community-based programs would utilize partnerships available within the area surrounding domestic violence shelters throughout the United States.

The major limitation for these programs will arise in rural communities that may not have a domestic violence shelter located nearby. In that case, these community-based programs may have to be hosted by other community centers, such as churches. However, hosting these programs at churches will create additional barriers or limitations when it comes to federal funding from VAWA due to First Amendment issues. Therefore, victims of IPV living in rural communities may not be able to receive benefits from these programs

and may instead have to rely on whatever domestic violence programs are currently available to them.

Additionally, as mentioned, the December 22, 2018 to January 25, 2019 federal government shutdown prevented VAWA from being reauthorized, causing it to lapse.⁹⁴ This throws into question the availability of VAWA funding for these community-based programs. According to the *Washington Post*, grants already awarded to states under VAWA will not be affected, but future payment requests from programs that receive VAWA funding will be delayed until VAWA is reauthorized, which is not guaranteed.⁹⁵ Without VAWA, grant applications to fund new programs will be placed at a standstill. If VAWA is not reauthorized, then states may be forced to allocate their own funding measures for new programs to address IPV.

Conclusion

Steady and consistent employment is a viable solution for alleviating the effects of IPV. Four federal laws should be considered to offer needed protections for victims of IPV: (1) the FMLA; (2) PPACA; (3) Title VII; and (4) VAWA. First, gap-filling state laws and FMLA should be amended to provide paid leave from work for victims of IPV to recover from the physical and/or mental effects of their abuse. Second, PPACA, if it survives its current constitutional challenge, should be amended to require applicable health insurance programs to cover more frequent and thorough screening and counseling for victims of IPV, which indirectly affects employment since it involves a woman's health. Third, Title VII and equivalent state laws should be amended to offer protections for victims in order to safeguard them from employment discrimination and/or employer retaliation. Finally, VAWA itself should not be amended, but if it is reauthorized, state domestic violence coalitions and other organizations

serving victims of IPV should apply for VAWA funding grants for community-based programs in order to strengthen state and local efforts to help IPV victims obtain employment. Even a change in just one of these areas would be a step in the right direction in dealing with this personal and public health issue.



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Before law school, she attended DePauw University, a small liberal arts college in Greencastle, Indiana. There, she began working with a non-profit medical organization and realized that she wanted to pursue public health and law. She further honed this interest during her internship with the Centers for Disease Control and Prevention's Public Health Law Program in Atlanta, Georgia, which is where she learned the process that she used to analyze laws for this article. Upon graduation, Ms. Hartman would like work within the health law field, specifically doing healthcare policy work on issues related to healthcare quality and access, telehealth/telemedicine, and the opioid epidemic. She would like to thank the ABA Health Law Section for choosing her paper to be featured in the *Health Lawyer*. She would additionally like to thank her health law professors for constantly pushing her to expand her health law knowledge base and supporting her in her writing and leadership endeavors. She may be reached at mthartman94@gmail.com.

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Lisa L. Dahm, Office of Harris County Attorney Vince Ryan, Houston, TX (Chair)

John D. Blum, Loyola University, Chicago School of Law, Chicago, IL

Robyn Whipple Diaz, St. Jude Children's Research Hospital, Memphis, TN

Marla Durben Hirsch, Editor, *The Health Lawyer*, Potomac, MD

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The writing competition is open to all current law students. Contact rachel.blakley@americanbar.org for information on the 2019 – 2020 competition.

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- ²⁸ *Id.*
- ²⁹ See *supra* note 9.
- ³⁰ *Texas et al., v. United States*, No. 4:18 -cv-00167-O (N.D. Tex. Dec. 14, 2018), <https://oag.ca.gov/system/files/attachments/press-docs/211-texas-order-granting-plaintiffs-partial-summary-judgment.pdf>. See also Julie Rovner, *Texas Judge Rules Affordable Care Act Unconstitutional, But Supporters Vow to Appeal*, NPR, (Dec. 14, 2018), <https://www.npr.org/sections/health-shots/2018/12/14/677002085/texas-judge-rules-affordable-care-act-unconstitutional-but-supporters-vow-to-app>.
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- ³² Jenny Gathright, *Violence Against Women Act Expires Because of Government Shutdown*, NPR, (Dec. 24, 2018), <https://www.npr.org/2018/12/24/679838115/violence-against-women-act-expires-because-of-government-shutdown>.
- ³³ 29 U.S.C.A. § 2612.
- ³⁴ 29 U.S.C.A. § 2614.
- ³⁵ *Id.*
- ³⁶ 29 U.S.C.A. § 2611.
- ³⁷ *Id.*
- ³⁸ *Id.*
- ³⁹ 29 U.S.C.A. § 2613.
- ⁴⁰ See *supra* note 9.
- ⁴¹ *Id.* at 737.
- ⁴² See *NFIB v. Sebelius*, 567 U.S. 519 (2012). Note that the Supreme Court ruling made such expansion optional; accordingly not all states have expanded Medicaid access.
- ⁴³ 124 Stat. 119.
- ⁴⁴ See *supra* note 30.
- ⁴⁵ Jane M. Liebschutz and Emily F. Rothman, *Intimate-Partner Violence—What Physicians Can Do*, N. ENG. J MED. 2071, 2071, November 29, 2012, available at: <https://www.calgaryfamilymedicine.ca/residency/dox/container/ADULT-DV&SA-What%20Physicians%20Can%20Do.pdf>.
- ⁴⁶ Health Resources & Services Administration, *Women's Preventive Services Guidelines*, September 2018, available at <https://www.hrsa.gov/womensguidelines/index.html>.
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- ⁴⁸ *Id.*
- ⁴⁹ 42 U.S.C. § 2000e-2.
- ⁵⁰ Equal Employment Opportunity Commission, *Overview*, available at <https://www.eeoc.gov/eeoc/index.cfm>.
- ⁵¹ *Hillware v. Snyder*, 151 F.Supp.3d 154, 155 (D.D.C. 2015).
- ⁵² *Id.*
- ⁵³ *Id.*
- ⁵⁴ *Id.* at 156.
- ⁵⁵ *Id.* at 158.
- ⁵⁶ *Lane v. Forever of PA, Inc.*, WL 9581864, *3 (W.D. Pa. 2015).
- ⁵⁷ *Id.*
- ⁵⁸ *Id.*, at *6.
- ⁵⁹ 34 U.S.C. § 12291(a)(8).
- ⁶⁰ 34 U.S.C. § 12431(a).
- ⁶¹ *Id.*
- ⁶² 34 U.S.C. § 12511.
- ⁶³ This particular list of jurisdictions was chosen for this mini survey because the states featured are a diverse mix of conservative and liberal states. As can be seen, not all states surveyed have laws related to IPV.
- ⁶⁴ Elissa Stone, *How the Family and Medical Leave Act Can Offer Protection to Domestic Violence Victims in the Workplace*, 44 U.S.F. L. REV. 729, 744, available at <https://repository.usfca.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1234&context=uslawreview>.
- ⁶⁵ West's Ann.Cal. Labor Code § 230(c).
- ⁶⁶ ILCS § 180/25.
- ⁶⁷ ILCS § 180/20(a)(1).
- ⁶⁸ ILCS § 180/20(2).
- ⁶⁹ West's Ann.Cal. Labor Code § 230(e).
- ⁷⁰ *Id.*
- ⁷¹ See https://maine.gov/ag/about/domestic_violence_policy.html.
- ⁷² See <https://malegislature.gov/Laws/SessionLaws/Acts/2014/Chapter260>.
- ⁷³ Note, this second goal, of preventing IPV in itself, is important but is beyond the scope of this article.
- ⁷⁴ ILCS § 180/20(a)(1.).
- ⁷⁵ Elizabeth Miller, Brigid McCaw, Betsy L. Humphreys, and Connie Mitchell, *Integrating Intimate Partner Violence Assessment and Intervention into Healthcare in the United States: A Systems Approach*, J. WOMEN'S HEALTH, Vol. 24, No. 1, 2015, 92, 92, available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4302956/pdf/jwh.2014.4870.pdf>.
- ⁷⁶ *Id.* at 94.
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- ⁷⁸ *Id.*
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- ⁸² Equal Employment Opportunity Commission, *Facts About Pregnancy Discrimination*, available at: <https://www.eeoc.gov/facts/fs-preg.html>.
- ⁸³ Stone, *supra* note 64, at 736.
- ⁸⁴ *Id.*
- ⁸⁵ 820 ILL. COMP. STAT. 180/30(b)(3) (2006).
- ⁸⁶ Rothman, et al., *How Employment Helps Female Victims of Intimate Partner Violence: A*

Qualitative Study, 12 J. OCCUP. HEALTH PSYCHOL., 136, 138, 2007, available at <https://pdfs.semanticscholar.org/4638/dcdb640a4063c51fd9cdf4463571ac299cff.pdf>.

- ⁸⁷ *Id.* at 141.
- ⁸⁸ Centers for Disease Control and Prevention and The National Center for Injury Prevention and Control, *National Intimate Partner & Sexual Violence Survey 2010-2012 State Report*, 206, April 2017, <https://www.cdc.gov/violenceprevention/pdf/NISVS-StateReportBook.pdf>.
- ⁸⁹ P.L. 93-247 (Jan. 31, 1974).
- ⁹⁰ Spivak et al., *CDC Grand Rounds: A Public Health Approach to Prevention of Intimate Partner Violence*, MMWR MORB. MORTAL. WKLY. REP., January 17, 2014, available at <https://europepmc.org/articles/pmc4584651>.
- ⁹¹ The Domestic Violence Prevention Enhancement and Leadership Through Alliances (DELTA) program seeks to reduce the incidence of IPV in funded communities by addressing the entire continuum of IPV from episodic violence to battering through a variety of activities at the individual, relationship,

community and society level influences. Note that this program ended in January 2013. See Centers for Disease Control & Prevention, *Domestic Violence Prevention Enhancement and Leadership Through Alliances (DELTA)*, available at <https://www.cdc.gov/violenceprevention/intimatepartnerviolence/delta/index.html>.

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- ⁹³ Congressional Research Service, *The Violence Against Women Act (VAWA): Historical Overview, Funding, and Reauthorization*, (Nov. 19, 2018), available at <https://fas.org/sgp/crs/misc/R45410.pdf>. VAWA has been reauthorized in 2000, 2005 and 2013.
- ⁹⁴ See *supra* note 32.
- ⁹⁵ Elise Viebeck, *Violence Against Women Act Expires with Government Shutdown*, *The Washington Post*, (December 22, 2018), available at https://www.washingtonpost.com/powerpost/violence-against-women-act-to-expire-with-government-shutdown/2018/12/21/b66f600a-0557-11e9-b5df-5d3874f1ac36_story.html?no-redirect=on&utm_term=.f0ad920166fd.

The Editorial Board provides expertise in specialized areas covered by the Section. Individual Board members were appointed by the Interest Group Chairs and Editor Marla Durben Hirsch. If you are interested in submitting an article to *The Health Lawyer*, you may contact one of the Editorial Board members or Ms. Hirsch. With the establishment of the Editorial Board, the Section strengthens its commitment to provide the highest quality analysis of topics in a timely manner.

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The Nominating Committee is pleased to announce the slate of candidates for Officers and Council members for FY 2020:

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Per Article VI, Section 1 of the Health Law Section Bylaws, notice is hereby given to the members of the Health Law Section. The election of such Officers and Council will occur at the Section Business Meeting during the ABA Annual Meeting in San Francisco in August.

If you have any questions or concerns, please contact **Simeon Carson**, Health Law Section Director, at simeon.carson@americanbar.org.

ABA Health Law Section Releases Comments on ONC's Interoperability Proposed Rule

The Health Law Section submitted comments on The Office of the National Coordinator for Health IT (ONC) proposed rule regarding the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program issued on March 4, 2019. The comments were approved by the Section's Council and submitted on May 30, 2019.

The comments were prepared jointly by a working group of the Health Law Section's eHealth, Privacy & Security Interest Group. A special thank you to: **Amy Fehn**, Health Law Office of Amy Fehn, Southfield, MI; **Matthew Fisher**, Mirick O'Connell, Westborough, MA; **Shana Graves**, USAbLe Life, Little Rock, AR; **Shannon**

Hartsfield, Holland & Knight, Tallahassee, FL and **Linda Malek**, Moses & Singer LLP, New York, NY.

The comments are available for review online at ambar.org/health.

Please note these views are presented only on behalf of the Section. They have not been approved by the ABA House of Delegates or Board of Governors and should not be construed as representing the policy of the American Bar Association.

If you have any questions or concerns, please contact **Simeon Carson**, Health Law Section Director, at simeon.carson@americanbar.org.



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CHANGES IN OWNERSHIP: MEDICARE RULES AND OTHER ISSUES

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Introduction

When a healthcare provider or supplier is enrolled in Medicare, certain transactions, including an asset transfer to a new owner, are typically classified by the Centers for Medicare & Medicaid Services (“CMS”) as a *change of ownership*, or CHOW, which requires notification from both seller and buyer, and CMS Regional Office (“RO”) approval. Such a transaction often results in formal assignment of the Medicare number and, if applicable, Medicare provider agreement, to the new owner. In comparison, transactions involving stock or membership transfers or other reorganizations that do not change the tax identification number (“TIN”) on file with CMS typically require the filing of an update of ownership information with CMS. However, CMS will ultimately make the final determination—based on the structure of the transaction—as to whether a CHOW has occurred. Therefore, notification of any changes in ownership information affecting a Medicare provider number is important to ensure that all CMS requirements and approvals are obtained. Failure to timely and properly notify CMS of a CHOW or update of ownership information can lead to deactivation or revocation of a Medicare identification number (also known as a Provider Transaction Number (“PTAN”) for Part B and CMS Certification Number (“CCN”) for Part A) or Medicare billing privileges.

When initially structuring and negotiating a transaction involving a Medicare provider or supplier, parties

to the transaction should review applicable Medicare regulations and CMS guidance to determine whether the proposed transaction is a CHOW or requires only an update of ownership information; understand applicable pre- and post-closing filing and notification requirements; determine whether regulations affect the proposed structure of the transaction; and identify other legal and business issues that may affect the transaction, such as successor liability and arranging for post-closing payment for Medicare services during the CHOW process.

Providers and Suppliers

When reviewing Medicare requirements relating to CHOWs and ownership updates, it is important to understand that Medicare classifies “providers” and “suppliers” as follows:

- *Providers* are defined generally to mean: (1) a hospital, critical access hospital, skilled nursing facility, comprehensive outpatient rehabilitation facility (“CORF”), home health agency, or hospice that has in effect an agreement to participate in Medicare; (2) a clinic, rehabilitation agency, or public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services; or (3) a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.¹ Providers typically use Form CMS-855A to notify CMS of a CHOW or update of ownership information.
- *Suppliers* are defined to mean a physician or other practitioner, or an entity other than a provider, that furnishes healthcare services under Medicare.² Suppliers include ambulance service providers, ambulatory surgery centers, clinics and group

practices, independent clinical laboratories, independent diagnostic testing facilities, and other healthcare services that bill under Medicare Part B. Suppliers typically use Form CMS-855B to notify CMS of a CHOW or update of ownership information. Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”) use Form CMS-855S.³

Medicare CHOWs

What Are Medicare CHOWs?

A Medicare change of ownership generally means:

- In the case of a *partnership*, the removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable state law.⁴
- In the case of a *sole proprietorship*, transfer of title and property to another party.⁵
- In the case of a *corporation*, the merger of the provider corporation into another corporation, or the consolidation of two or more corporations, resulting in the creation of a new corporation.⁶ An asset transfer of a corporation would be considered a CHOW, whereas the transfer of corporate stock or the merger of another corporation into the provider corporation typically would not.⁷
- Medicare regulations and guidelines do not specifically address *limited liability corporations* (“LLCs”). CMS recognizes that LLCs have characteristics of both a partnership and corporation and that the members in an LLC are very similar to those of stockholders in corporations.⁸ It is common for CMS to view an asset transfer involving an LLC as a CHOW but, similar to

transfer of corporate stock, not treat a transfer of a membership interest in an LLC as a CHOW.

Although a CHOW is usually accompanied by a TIN change, this is not always the case. The RO will review the sales agreement closely to definitively determine whether a CHOW has occurred.⁹ To identify ownership, the RO will determine which party (whether an individual or legal entity such as a partnership or corporation) has immediate authority for making final decisions regarding the operation of the provider and bears the legal responsibility for the consequences of the provider's operations.¹⁰

A CHOW may also occur in certain situations involving leases.¹¹ Whether the provider's premises are directly owned or rented or leased from a landlord or lessor is immaterial. However, if the owner enters into an agreement that allows the "landlord" to make or participate in decisions about the ongoing operation of the provider enterprise, this indicates that the owner has entered into either a partnership agreement or a management agency agreement instead of a property lease, and such transaction would likely be considered a CHOW.¹² Furthermore, the leasing of all or part of a facility used to render patient care will be considered a CHOW if the leasing affects utilization, licensure, or certification of the entity enrolled in Medicare.¹³

Arrangements between a provider or supplier and a management company do not typically result in CHOWs. A management company that contracts with owners to provide management services, subject to the owners' general approval of operating decisions, is considered an agent of the owners rather than a partner or successor. This is the case even if the management company appears to have wide latitude in making decisions and even if the management fee is based on the net revenue or profit the provider or supplier receives from furnishing services.¹⁴ The only case in which operation under a management

agreement would constitute a CHOW is when the owner has relinquished all authority and responsibility for the provider organization.¹⁵

CHOW Notification and Filing Requirements

Providers

When a provider undergoes a CHOW, the current owner (seller) and the prospective new owner (buyer) must complete and submit to the provider's designated Medicare Administrative Contractor ("MAC") a CMS 855-A and other forms and documentation relating to the transaction.¹⁶ To help promote a seamless transaction and faster review, the buyer and seller must submit their applicable CMS-855A forms to the MAC around the same time, but no later than 14 days from each other.¹⁷ The MAC may accept Form CMS-855A CHOW applications submitted up to 90 calendar days prior to the anticipated date of the ownership change.¹⁸ The MAC will process the CMS-855A forms and forward to the appropriate state survey agency ("SA") its recommendations and final Form CMS-855.¹⁹ After the SA concludes its factfinding, it forwards the findings, with supporting documentation, to the RO with its recommendations for determination. The RO will make the final determination regarding whether the transaction qualifies as a CHOW.²⁰

Approved Suppliers

The Medicare CHOW provisions apply to Medicare providers and certain Medicare suppliers that require approval through certification survey by the state surveying agency or through accreditation such as portable X-ray suppliers, ambulatory surgery centers, and hospitals with departments that bill for Medicare Part B services.²¹ Other types of suppliers, such as a group practice, are not permitted to undergo a CHOW; a new owner must newly enroll as a Part B supplier in the event a transaction that constitutes a CHOW occurs.²² In anticipation of a CHOW, the new

owner of an approved supplier must submit a complete Form 855B and submit a copy of the sales agreement to the MAC. The CHOW must be reported to the MAC within 30 days of the change.²³ However, a CMS-855B CHOW application may be accepted by the MAC up to 90 calendar days prior to the anticipated date of the proposed ownership change.²⁴ The MAC will review the sales agreement submitted with a CMS-855B application indicating a CHOW to determine whether: (1) the ownership change qualifies as a CHOW under the principles of 42 C.F.R. § 489.18; (2) its terms indicate that the new owner will be accepting assignment of the Medicare assets and liabilities of the old owner; and (3) the information contained in the agreement is consistent with that reported on the new owner's Form CMS-855B (e.g., same names provided).²⁵ However, the RO—not the MAC—makes the final determination regarding whether a CHOW has occurred.²⁶

Assignment of the Provider Agreement

CMS will automatically assign the existing provider agreement to the new owner unless the new owner rejects assignment in its Form 855 filings.²⁷ With automatic assignment, the new owner becomes subject to all of the terms and conditions under which the existing agreement was issued, including, but not limited to:

1. Any existing plan of correction.²⁸ The new owner must meet the time frames for correcting deficiencies cited in the existing plan of correction. A CHOW is not a basis for extending the time given for correction.²⁹
2. Compliance with applicable health and safety standards.³⁰ Assignment of an existing provider agreement assumes that a CHOW will have no adverse effect on patient health and safety. If there is any indication that patient care has deteriorated following a CHOW, the SA must conduct a survey.³¹

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Changes in Ownership: Medicare Rules and Other Issues

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3. Compliance with the ownership and financial interest disclosure requirements applicable to the provider.³²
4. Compliance with civil rights non-discrimination requirements.³³

With automatic reassignment, the new owner assumes all penalties and sanctions under the Medicare program, including the repayment of any accrued overpayments, regardless of who had ownership of the Medicare agreement at the time the overpayment was discovered unless, under certain circumstances, fraud was involved.³⁴ In addition, the new owner receives any benefits of assuming the Medicare provider agreement, such as receiving underpayments discovered after the CHOW.³⁵ A sales agreement stipulating that the new owner is not liable for overpayments made to the previous owner is not evidence enough for recovery from the new owner to be avoided; however, the parties may privately negotiate indemnification for such losses. Medicare will attempt to recover from the new/current owner regardless of the sales agreement, and it would be up to the new owner to enforce the sales agreement.³⁶ If CMS is unable to recover an overpayment from the current/new owner, CMS may decide to collect the overpayment from the previous owner.³⁷

If the new owner rejects automatic assignment of the seller's existing provider agreement or, if applicable, supplier approval, the existing Medicare provider agreement—including the associated Medicare numbers—is considered voluntarily terminated.³⁸ The voluntary termination is effective as of the date the acquisition is completed, and, with few exceptions relating to certain providers like skilled nursing facilities, no Medicare payments are made for services to beneficiaries under the rejected (and thus terminated) provider agreement furnished on or after that acquisition date.³⁹

The refusal to accept assignment must be put in writing by the prospective new owner and forwarded to the appropriate CMS RO 45 calendar days prior to the CHOW date to allow for the orderly transfer of any beneficiaries that are current patients.⁴⁰ If the new owner refuses to accept assignment but also wishes to participate in the Medicare program, the RO will first process the refusal and then treat the new owner as it would any new applicant to the program.⁴¹ The earliest possible effective date of Medicare enrollment for the new owner that refuses automatic assignment is the date the RO determines that all federal requirements have been met. The federal requirements include, in addition to the Conditions of Participation, enrollment and any other special requirements applicable to specific providers. A new Medicare number will be issued at some time after closing, depending on how long it takes to meet all federal requirements. Consequently, if the new owner refuses assignment and applies for a new Medicare number, there will be a gap between the date of the CHOW and the effective date of the new Medicare number.

New Certification Surveys

A certification survey of the provider is generally not required as a result of a CHOW with automatic assignment; however, a CMS RO may exercise its discretion to direct the state survey agency to conduct a survey in individual cases when it has cause for concern about quality of care.⁴² Furthermore, if new locations are added or different types of services will be provided, a new survey may be required.⁴³ In the case of deemed status providers or suppliers, automatic assignment also means that the new owner must notify the applicable accrediting organization ("AO") of the acquisition and agree that accreditation continues until the AO decides whether a resurvey is necessary.⁴⁴

If the new owner rejects automatic assignment, but wishes to participate in the Medicare program, the facility under the new ownership is considered an initial applicant to the Medicare program.⁴⁵ For providers subject to certification, this means that, in addition to completing the Form 855 enrollment process, they must also satisfy any other applicable federal Medicare participation requirements, including undergoing an unannounced full survey of the compliance with applicable Medicare requirements.⁴⁶ If the seller was deemed to meet the applicable conditions based on its accreditation under a CMS-approved Medicare accreditation program, the AO may not extend its prior accreditation of the new owner, but must conduct a full initial accreditation survey after the acquisition date. The effective date of the new owner's Medicare provider agreement or supplier approval is calculated based on the time of the accreditation survey and decision.⁴⁷

Initial certification surveys are subject to a number of requirements, which result in gaps between the date of an acquisition and the effective date of a Medicare enrollment for a provider or certain types of suppliers that reject automatic assignment. Specifically:

- State survey agencies or AOs must not conduct a survey for initial certification purposes until after the date the acquisition is complete; the survey must be a full, standard survey and must take place when the facility is under its new ownership in order to assess compliance of the new owner.⁴⁸
- The survey cannot be conducted until the applicable MAC has issued a recommendation for approval of the new owner's enrollment application.⁴⁹
- The new owner must be fully operational and providing services before it may be surveyed.⁵⁰

- CMS workload instructions, issued on November 5, 2007, require initial surveys conducted by SAs generally to be the lowest workload priority, particularly in the case of provider or supplier types for which there is an accreditation option.⁵¹ Due to these workload priorities, it may take several years for an SA to conduct an initial accreditation survey.

A buyer that rejects automatic assignment of the seller's Medicare number but wishes to participate in the Medicare program must be aware of the potential gaps in certification and enrollment and the impact on cash flow. The provider or supplier undergoing the CHOW will not be able to bill Medicare or receive payment for services provided during this gap period.

Cost Reports

When providers that are required to file Medicare cost reports undergo a CHOW, Medicare regulations require the seller to file a final cost report, which should cover the period from the end of the provider's prior cost reporting period to the effective date of the CHOW.⁵² The final cost report is due no later than five months following the effective date of the CHOW.⁵³ Items to be considered in the seller's cost report include: (1) gains and losses on disposal of depreciable assets; (2) accelerated depreciation; (3) involuntary conversion losses; (4) demolition and abandonment losses; (5) lease-purchase agreements/rental charges; (6) start-up and organization costs; (7) self-insurance; (8) insurance purchased from a limited-purpose insurance company; (9) administrative costs incurred after change of ownership; (10) tentative retroactive adjustment; (11) carryover of reasonable cost not reimbursed due to the "lower of reasonable cost or customary charges" provision; and (12) cost to related organizations.⁵⁴

The new owner can designate its cost reporting year.⁵⁵ In a CHOW, the new owner is considered to be a new

provider in the program and may file its initial cost report covering a period of at least one month of provider operations, but the cost report cannot exceed 13 months of operations under the program.⁵⁶ A change in provider ownership may have an immediate effect on the manner in which the new or incoming provider is reimbursed for Medicare services. Some of the reimbursement areas requiring special treatment on the new provider's cost report include: (1) basis of depreciable assets; (2) donated assets; (3) involuntary conversion losses; (4) demolition and abandonment losses; (5) recovery of accelerated depreciation; (6) startup costs; and (7) organizational costs.⁵⁷

Payment Issues Associated with a CHOW

When a CHOW involving automatic reassignment is pending, Medicare will continue to pay the previous owner (seller) until the CHOW is approved by the CMS RO and a final tie-in notice is issued.⁵⁸ When a CHOW is pending, any application from the old or new owner to change the electronic funds transfer ("EFT") account or special payment address to that of the new owner will be rejected by the MAC.⁵⁹

CMS advises that it is ultimately the responsibility of the old and new owners to work out any payment arrangements between themselves while the MAC and CMS RO are processing the CHOW.⁶⁰ Therefore, if the buyer wishes to continue billing Medicare under the existing Medicare number while a CHOW is pending approval, the parties to the transaction should negotiate terms for handling the funds received by the seller during this transition period. Parties to a transaction involving a provider that bills under the Prospective Payment System ("PPS") should also be aware of billing requirements relating to patients whose episode of care straddles between buyer and seller.⁶¹ Payment is determined by date of

discharge, and CMS does not prorate payment between buyer and seller. Other payments for cost-reimbursed capital payments, direct medical education, certain anesthesia services, organ acquisition, and bad debt are made to the buyer and seller in accordance with the principles of reasonable cost reimbursement.⁶² Parties to a CHOW should be aware of these payment implications when negotiating the terms of the purchase agreement or other agreements ancillary to the transaction.

Medicare Updates of Information

Not all transactions involving a Medicare provider or supplier result in a CHOW. For example, stock transfers in a corporation, even if such transfer involves 100 percent of the stock ownership, typically do not result in a CHOW.⁶³ Instead, such transactions require an update of the ownership information on file with CMS for the current Medicare number. This update is accomplished by filing a Form CMS-855A, CMS-855B, or CMS-855S with the applicable MAC. Updates of ownership information may be filed by some suppliers, such as a group practice, that are not permitted to undergo a CHOW.

Most changes to a provider's or supplier's enrollment information must be filed with the MAC within 90 days of the change.⁶⁴ Medicare regulations specify that providers and suppliers (other than physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, registered dietitians or nutritional professionals, and organizations [e.g., group practices] consisting of any of the categories of the preceding individuals) must report a "change of ownership or control, including changes in authorized official(s) or delegated official(s)" within 30 days.⁶⁵ CMS's reference to a

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change of “control” leaves some uncertainty as to whether providers and suppliers must report a stock transfer, or similar change of information relating to control, within 30 or 90 days. Historically, a transaction that does not qualify as a CHOW has been treated as an update of information, for which updates must be filed within 90 days. However, DMEPOS suppliers must report any changes in information supplied on the enrollment application, including a change of ownership information that does not change the current TIN, within 30 days of the change to the National Supplier Clearinghouse (“NSC”).⁶⁶

Once an “855” update of ownership or control information is filed with the MAC, the MAC will send the update to the RO for approval. However, if the transaction is a stock transfer, the MAC may not send the transaction to the SA/RO if the following three conditions are met: (1) the contractor is confident that the transaction is merely a transfer of stock and not a CHOW; (2) the RO in question (based on the contractor’s past experience with this RO) does not treat stock transfers as potential CHOWs; and (3) the contractor knows that the particular SA/RO in question does not review, approve, or deny this type of transaction.⁶⁷

Failure to Report a CHOW or Update of Ownership Information

Failure to file a CHOW or change of information within the applicable 90-day or 30-day reporting period may result in deactivated billing privileges⁶⁸ or revocation of the provider’s or supplier’s Medicare number.⁶⁹ If an incomplete enrollment application is submitted, CMS may also deactivate the Medicare billing number based upon material omissions in the submitted enrollment application, or

based on preliminary information received or determined by CMS that makes CMS question whether the new owner will ultimately be granted a final transfer of the provider agreement.⁷⁰

Additional Considerations for Certain Providers/Suppliers

Home Health Agencies

Under the home health “36-month rule,” which applies to home health agency transactions effective on or after January 1, 2011, if a majority ownership of a home health agency changes by sale (including stock transfers, mergers, consolidations and transfers) within 36 months of the home health agency’s Medicare enrollment or prior change of majority ownership, the provider agreement and Medicare billing privileges will not be conveyed to the new owner.⁷¹ The prospective provider/owner of the home health agency must instead enroll in the Medicare program as a new (initial) home health agency and obtain a state survey or accreditation from an approved AO.

There are four primary steps to follow to determine whether the 36-month rule applies to a home health transaction:

1. Determine whether a change in direct ownership has occurred. The 36-month rule does not apply to “indirect” ownership changes.⁷²
2. Determine whether the change involves a party assuming a greater than 50 percent ownership interest in the home health agency. For purposes of the 36-month rule, a “change in majority ownership” occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a home health agency during the 36 months following the home health agency’s initial enrollment in the Medicare program or the 36

months following the home health agency’s most recent change in majority ownership (including asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the home health agency’s most recent change in majority ownership).⁷³

3. Determine whether the effective date of the transfer is within 36 months after the effective date of the home health agency’s initial enrollment in Medicare or most recent change in majority ownership. If the effective date of the transfer does not fall within either of the aforementioned 36-month periods, the 36-month rule does not apply.⁷⁴
4. Determine whether any of the following exceptions apply: (1) if the home health agency submitted two consecutive years of full cost reports (low utilization or no utilization cost reports do not qualify as full cost reports); (2) a home health agency’s parent company is undergoing an internal corporate restructuring, such as a merger or consolidation; (3) the owners of an existing home health agency are changing the home health agency’s existing business structure (for example, from a corporation to a partnership [general or limited]; from an LLC to a corporation; from a partnership [general or limited] to an LLC) and the owners remain the same); or (4) the individual owner of a home health agency dies, regardless of the percentage of ownership the person had in the home health agency.⁷⁵

If a change in majority ownership has occurred within the previous 36 months and none of the exceptions apply, the home health agency must enroll as a new entity in Medicare if the parties move forward with the transaction.⁷⁶ As previously discussed, new enrollment for the home health

agency would require filing a CMS 855-A for initial enrollment and a new certification survey and deemed accreditation, which cannot occur prior to the transaction or before the MAC processes the initial enrollment application.

Subunits

Providers that have subunits and undergo a CHOW may need to file multiple CMS-855 forms to transfer the subunits to the new owner. Any subunit that has a separate provider agreement (e.g., home health agency subunits) must report its CHOW on a separate Form CMS-855A rather than using the main provider's CMS-855A.⁷⁷ However, if the subunit has a separate Medicare provider number but not a separate provider agreement (e.g., hospital psychiatric unit, home health agency branch), the CHOW can be disclosed on the main provider's Form CMS-855A because the subunit is treated as a practice location of the main provider and not a separately enrolled entity.⁷⁸

Subtypes

On occasion, a CHOW may occur in conjunction with a change in the facility's provider subtype. This can happen when a hospital undergoes a CHOW and changes from a general hospital to another type of hospital, such as a psychiatric hospital. Although a change in hospital type is considered a change of information, all information (including the change in hospital type) should be reported on the CHOW application, and the entire application will then be processed as a CHOW.⁷⁹ However, if the facility is changing from one main provider type to another (e.g., hospital converting to a skilled nursing facility) and also undergoing a CHOW, the provider must submit its application as an initial enrollment.⁸⁰

DMEPOS Suppliers

Updates of information and CHOWs involving a DMEPOS supplier are processed by the NSC. All

updates of ownership information or CHOWs must be reported to the NSC within 30 days. Failure to timely report such changes to the NSC within the required 30-day period will lead to a revocation action.⁸¹

If a DMEPOS supplier undergoes a CHOW, the buyer must obtain accreditation that covers all of the supplier's locations.⁸² If the seller has such an accreditation, the buyer can be enrolled as of the date of sale if the accreditor determines that the accreditation should remain in effect as of the date of sale.⁸³ If the buyer submits an application without evidence that the accreditation is still in effect for the buyer, CMS has instructed the NSC to reject the application.⁸⁴

Effective May 4, 2009, DMEPOS suppliers submitting an enrollment application to change the ownership of an existing supplier are also required to obtain and submit a copy of that supplier's required surety bond to the NSC with the CMS-855S enrollment application. The surety bond must be in an amount of not less than \$50,000 and is predicated on the National Provider Identifier ("NPI"), not the TIN.⁸⁵ Thus, if a supplier has two separately enrolled DMEPOS locations, each with its own NPI, a \$50,000 bond must be obtained for each site.⁸⁶ Ownership changes that do not involve a change in the status of the legal entity (as evidenced by no change in the TIN), or changes that result in the same ownership at the level of individuals (corporate reorganizations and individuals incorporating) are not considered to be "changes of ownership" for purposes of the May 4, 2009 effective date.⁸⁷

DMEPOS Suppliers Participating in Competitive Bidding

DMEPOS suppliers participating in the Competitive Bidding Program have additional CHOW filing requirements relating to their contracts. A DMEPOS supplier that is negotiating a CHOW must notify CMS at least 60 days before the anticipated date of the

change.⁸⁸ Contract suppliers that do not notify CMS of a CHOW are in breach of their contract.⁸⁹

A CHOW does not automatically grant contract supplier status of the new owner; however, CMS may permit the transfer of a competitive bidding contract to an entity that merges with or acquires a competitive bidding contract supplier if the new owner assumes all rights, obligations, and liabilities of the competitive bidding contract. CMS divides filing requirements relating to a CHOW into two groups: one for "successor" entities and the other for "new" entities. A *successor entity* is an existing entity that merges with or acquires a contract supplier and continues to exist after the CHOW as it existed before the transaction. A *new entity* is an entity that is formed as a result of merger or acquisition and did not exist prior to the transaction.

CMS may award a contract to the new or successor entity if: (1) the entity meets all requirements applicable to contract suppliers for competitive bidding program(s) to which the contract supplier's contract applies; and (2) the entity submits to CMS documentation needed to substantiate compliance with basic eligibility requirements, quality standards, accreditation requirements, and financial standards.⁹⁰

The parties must also prepare a novation agreement that is signed by all parties involved in the contract transfer, including CMS. CMS will review all novation agreements and will only accept those that assign all applicable contract supplier obligations to the purchaser. An acceptable novation agreement should include a number of provisions specified by CMS through guidance.⁹¹ A sample novation agreement can be found at 42 C.F.R. § 42.1204. If the transaction involves a successor entity, an executed novation agreement must be submitted to CMS at least 30 calendar days before the anticipated effective date of the change of ownership.⁹² If a

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CHOW involves a new entity, the existing contract supplier must submit its final draft of a novation agreement to CMS at least 30 days before the anticipated effective date of the CHOW. The new entity must submit an executed novation agreement to CMS within 30 days after the effective date of the CHOW.⁹³

In the event of a CHOW or even a change of ownership interest of at least five percent (including a stock transfer), DMEPOS suppliers participating in the Competitive Bidding Program will have reporting obligations to the Competitive Bidding Implementation Contract ("CBIC") as well as the NSC. For example, for stock purchases that result in five percent or more ownership transfers, the seller must notify the CBIC by mailing or faxing all pertinent information regarding the transaction and include all information sent to the NSC.⁹⁴

Conclusion

When engaging in an acquisition involving a Medicare provider or supplier that results in a CHOW, buyer and seller parties should address various Medicare requirements to ensure that appropriate and timely filings are made to assign or obtain a Medicare number, and should also plan for how the transaction may affect post-closing Medicare payments. Buyers must consider whether to accept assignment of the seller's Medicare number and, if not, the business impact involved with enrolling as a new provider or, if applicable, supplier. For transactions that qualify as updates of information, rather than CHOWs, it is also important for the parties to ensure that ownership updates are appropriately and timely filed. Failure to properly handle CHOWs or updates of information could result in deactivated billing privileges or

revocation of the provider or supplier Medicare number.

* * *

This article is adapted from the ABA Health Law Section's new book, What is ...CHOW? The book provides readers with a general understanding of the regulatory and other processes involved when a healthcare provider or supplier undergoes a change in ownership. For more information, go to www.shopABA.org.



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Endnotes

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- 2 42 U.S.C. § 1395x(d); 2 C.F.R. § 400.202.
- 3 Centers for Medicare & Medicaid Services, PROGRAM INTEGRITY MANUAL ch. 15, § 15.1.2 [“CMS PROGRAM INTEGRITY MANUAL”].
- 4 42 C.F.R. § 489.18(a)(1); Centers for Medicare & Medicaid Services, CMS MANUAL SYSTEM PUB. 100-07 STATE OPERATIONS MANUAL, ch. 3, § 3210.1.D.2 [“CMS STATE OPERATIONS MANUAL”].
- 5 42 C.F.R. § 489.18(a)(2); CMS STATE OPERATIONS MANUAL § 3210.1.D.1.
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- 12 *Id.*
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- 15 *Id.*
- 16 42 C.F.R. § 424.550(b).
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- 24 CMS PROGRAM INTEGRITY MANUAL § 15.7.8.3.1.
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- 29 CMS STATE OPERATIONS MANUAL § 3210.
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- 32 See 42 C.F.R. §§ 420.200420.206.
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- 35 *Id.*
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- 38 CMS STATE OPERATIONS MANUAL, § 3210.5A.
- 39 CMS, Letter to State Survey Agency Directors, “Acquisitions of Providers/Suppliers with Rejection of Automatic Assignment of the Medicare Provider Agreement: Implications for Timing of Surveys and Participation Effective Date” (Sept. 6, 2013) [“CMS State Survey letter”].
- 40 CMS STATE OPERATIONS MANUAL § 3210.5A.
- 41 *Id.*
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- 46 *Id.*
- 47 CMS State Survey letter; 42 C.F.R. § 489.13.
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- 51 Department of Health & Human Services, Centers for Medicare & Medicaid Services, Letter to State Survey Agency Directors, “Initial Surveys for New Medicare Providers” (Nov. 5, 2007).
- 52 Providers required to file Medicare Cost Reports include hospitals, home health agencies, hospices, CORFs, independent renal dialysis facilities, skilled nursing facilities, independent rural health clinics, and federally qualified health centers (“FQHCs”).
- 53 Centers for Medicare & Medicaid Services, MEDICARE PROVIDER REIMBURSEMENT MANUAL, Part 2, Ch. 1, § 104B [“CMS MEDICARE PROVIDER REIMBURSEMENT MANUAL”]; 42 C.F.R. § 413.24(f)(2).
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- 58 CMS PROGRAM INTEGRITY MANUAL § 15.7.7.1.5.
- 59 *Id.*
- 60 *Id.*
- 61 See 42 C.F.R. § 412.125.
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- 63 42 C.F.R. § 489.18(a)(3).
- 64 42 C.F.R. § 424.516(d), (e); 42 C.F.R. § 410.33(g).
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- 77 CMS PROGRAM INTEGRITY MANUAL § 15.7.7.1.3(E).
- 78 *Id.*
- 79 *Id.*
- 80 *Id.*
- 81 CMS PROGRAM INTEGRITY MANUAL § 15.21.1.
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- 89 42 C.F.R. § 414.422(g).
- 90 42 C.F.R. § 414.422(d)(2); 42 C.F.R. § 414.414(b)(d); Centers for Medicare & Medicaid Services, CMS MANUAL SYSTEM PUB. 100-04, MEDICARE CLAIMS PROCESS MANUAL, ch. 36, § 30.7 [“CMS CLAIMS PROCESS MANUAL”].
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