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April 2009 Monthly Newsletter

FEATURED ARTICLES

The Proposed Patent Reform Act of 2009 - Impact on the Pharma Industry

By Jess Ebert, CIS Compliance Associate

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For the past two years patent reform efforts have failed due in part to vehement opposition by pharmaceutical companies. However, it is a new year with a new administration, so it appears that it is time for another try. On March 3rd 2009, new patent reform legislation was again introduced in both the Senate and the House of Representatives by Senator Patrick Leahy (D-VT), Senator Orrin Hatch (R-UT), with companion legislation by Representative John Conyers, JR. (D-MI) and Representative Lamar Smith (R-TX). The Patent Reform Act of 2009 closely mimics that of 2007 and has once again stirred the fires of pharma companies, big and small, brand and generic manufacturers alike. There are two controversial provisions that especially affect the pharmaceutical industry: damage apportionment and inequitable conduct.

Damage Apportionment- Current infringement damages consider the entire market value of pharmaceutical products. The proposed reform would determine damages based on the "specific contribution over the prior art." Reasonable royalties would be determined as the price of licensing a "similar non-infringing substitute in the relevant marketplace." In addition to these changes, limitations on treble damages for willful infringement have been introduced. An adjudged infringer would have to be found "objectively reckless" in continuing to infringe (even after receiving written notice from the patentee) in order to accrue treble damages.¹

In 2007 and 2008, high-tech and pharmaceutical companies failed to agree on whether damages for infringement should be reduced. In the Patent Reform Act of 2009, not much has changed. The devices that high-tech companies sell can have many patented components and because of this, they still favor a reduction in damages in order to deter "unwarranted" lawsuits. Pharmaceutical companies, on the other hand, manufacture drugs that only have one or two patents. Lowering penalties would leave them vulnerable to infringers and risk the protection of intellectual property.²

Senior Vice President Ken Johnson of the Pharmaceutical Research and Manufacturers of America (PhRMA) issued a press release on March 3, 2009 stating PhRMA's opinion on the proposed act. "A strong and reliable patent system...is especially important for pharmaceutical and biotechnology innovators that are faced with the daunting average investment of 10 to 15 years and roughly one billion dollars to develop a new drug." In relation to damage apportionment, Johnson says that "unfortunately, a reduction in penalties- or damages- will clearly put the promise of IP protection at risk by leaving patent holders unable to recover their losses if infringed."³ This statement has been echoed by many pharmaceutical companies, contesting that even the current large damage awards are barely enough to cover the litigation fees of infringements.⁴ Fears are also rising that lowering damages will ultimately reduce the value of patents and lead to further economic challenges by decreasing the jobs associated with innovative industries.²

As Senator Hatch introduced the bill to Congress on March 3, 2009, he made it a point to comment on the concerns about damage apportionment. Current law allows for damages to be based on market value for the entire product, but there are situations where only a small component of the product was infringed upon. However, lowering damages could encourage infringing behavior. Hatch states "I am confident that we will achieve consensus language in this area, but make no mistake: It will take willing partners to craft a compromise that will not have deleterious effects on any one sector of our economy."⁵

Inequitable Conduct Doctrine- According to the current doctrine, even if a patent is valid and infringed, it may be unenforceable in the courts if it is found that the patentee has engaged in inequitable conduct. Such conduct is characterized by misrepresenting or omitting material facts with the intent on deceiving the United States Patent Office.

The Patent Reform Act of 2009 does not include provisions on inequitable conduct, but Senator Hatch acknowledged the importance of this provision. "Inequitable-conduct reform is core to this bill, as it dictates how patents are prosecuted years before litigation. The inequitable-conduct defense is frequently pled, rarely proven, and always drives up the cost of litigation tremendously."⁵

Continued on Page 2...

FEATURED ARTICLES

**The Proposed Patent Reform Act of 2009-
Impact on the Pharma Industry**
By: Jess Ebert

**Pharmaceutical and Medical Device
Manufacturer Conduct Regulation Finalized!**
By: Justin Wutti

TRICARE CORNER

The TRICARE Final Rule!
By: Dana Zelig

**Bill Baxter Brings Extensive Pharmaceutical
Government Programs Expertise to CIS**
By: Jackie O'Connor

LETTER FROM THE EDITOR

Legal Documents 101

By: Meredith Taylor, Esq.
Editor-In-Chief and PCX Product Manager

Continued from Page 1...

From Senator Hatch's statement, it would seem that the development of a more objective inequitable conduct doctrine would be the next step. However, as with damage apportionment, there are concerns with revising this provision as well. The Generics Pharmaceutical Association (GPhA) President and CEO Kathleen Jaeger issued a statement on March 4, 2009 responding to the proposed reform. Jaeger stated that "weakening the inequitable conduct penalty will simply result in providing brand companies with a greater incentive to be dishonest and cheat, making it harder for companies to bring affordable generic medications to consumers sooner." Jaeger goes on to say that the reform is about jobs, innovation, and consumers and that "[they] are committed to ensuring that reforms do not have the unintended consequences of erecting any barriers to the introduction of generic medicines that may help consumers save money, particularly in these difficult economic times."⁶

Damage apportionment and inequitable conduct are the two key issues of the patent reform, and the most likely to directly affect the pharma industry. Both PhRMA and GPhA have expressed their concerns with the proposed reform: PhRMA focuses on how damage apportionment will affect companies facing costly infringement and the devaluation of patents while GPhA is concerned with the affects of weakening the inequitable conduct doctrine. Careful consideration must be given to both of these issues in order to craft a fair and well-reasoned patent reform. In the words of Senator Hatch "Now is the time to act."

¹ <http://www.patentlyo.com/patentreformactof2009.pdf>

² http://www.wired.com/techbiz/media/news/2009/03/reuters_us_patents

³ http://www.phrma.org/news_room/press_releases/phrma_statement_on_patent_reform_act_of_2009/

⁴ <http://www.eweek.com/c/a/IT-Management/Hatch-Predicts-Patent-Reform-Victory-773821/>

⁵ http://hatch.senate.gov/public/index.cfm?FuseAction=PressReleases.Detail&PressRelease_id=ce28c6f0-1b78-be3e-e028-418ea18126e5

⁶ <http://www.gphaonline.org/media/press-releases/2009/gpha-statement-regarding-introduction-patent-reform-act-2009>

Pharmaceutical and Medical Device Manufacturer Conduct Regulation Finalized!

By: Justin Wutti, CIS Senior Compliance Associate

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As CIS has previously reported in the January and March 2009 newsletters, Massachusetts has been working to finalize its proposed regulation which limits relationships between **Pharmaceutical and Medical Device Manufacturers and Health Providers**.

The proposed regulation was created to interpret and implement the Massachusetts healthcare reform bill enacted in August 2008, entitled, "An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Healthcare" (Chapter 111N) . Among other things, Chapter 111N requires the Massachusetts Department of Public Health (DPH) to establish a marketing code of conduct, and any pharmaceutical or medical device manufacturer that sells or markets prescription drugs in MA is required to adopt this code of conduct, as well as comply with other compliance and reporting requirements. The Act also required the DPH to create and publish regulations to carry out its intent.

The proposed regulation was published in December 2008 to comply with Chapter 111N, and a comment period extended for a few months thereafter. On March 11, 2009, the DPH Public Health council approved a final regulation that will go into effect on **July 1, 2009**.

While the final regulation encompasses most of what was in the proposed regulation, there were some significant changes. An analysis of the contents of the proposed regulation can be found in the January and March 2009 newsletters. The following is a summary of the changes that appear in the final regulation:

- In regards to the restrictions on payments to health care practitioners, the list of permitted activities was expanded to include the following:
 - "Reasonable quantities of medical device demonstration and evaluation units provided to a health care practitioner to assess the appropriate use and functionality of the product and determine whether or not and when to use or recommend the product in the future."
 - "Charitable donations, provided that the donation is not provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices...and does not otherwise violate the provisions of 105 C.M.R. 970.000.
 - "Reasonable compensation for bona fide services."

Continued on Page 3...

[HOME](#)

Continued from Page 2...

- A proposed CME provision that prohibited “financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other health care professionals in training to attend educational conferences” was deleted.
- The calculation of the \$50 threshold for fees, payments, subsidies, and other economic benefits shall be on an individual transaction basis rather than be aggregated.

The regulation now states that a person must “knowingly and willfully” violate 105 CMR 970.000 to incur the \$5,000 penalty. The proposed regulation was not dramatically revised in the final version; in fact, the majority of the proposed regulation remains intact in the final regulation. Most importantly, as was mandated in the proposed regulation, on **July 1, 2010**, companies must submit the first annual reports certifying that they were compliant with the marketing code of conduct in the previous year.

For the final regulation, log into the GP PCX and click on Hot Topics, or click [HERE](#).

TRICARE CORNER

The TRICARE Final Rule was published last month, and CIS has been closely following the developments and posting blog articles at <http://www.pharmacomplianceblog.blogspot.com/>. The following article summarizing the TRICARE Final Rule is being re-printed as it appeared on the CIS Pharma Compliance Blog on Wednesday March 18, 2009. Also, these articles have also been posted to the blog and we urge you to check them out if you have not done so already:

1. [The TRICARE Final Rule: What's in the Comments?](#) By Clarissa Crain, CIS Director of Operations and Audit
2. [CIS' TRICARE Final Rule Teleconference](#) By Dave Rice, CIS Director Federal Contracting
3. [TRICARE Guidance Documents Available on the TMA Website](#) By Meredith Taylor, Esq., CIS Senior Compliance Manager

The TRICARE Final Rule!

By Dana Zelig: CIS Senior Compliance Associate

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Well readers, it has finally happened. The Department of Defense (DoD) has published the TRICARE Final Rule it has been working on since January 28, 2008. On March 17, 2009, [Federal Register Vol. 74, No. 50](#) announced the TRICARE Final Rule: Inclusion of TRICARE Retail Pharmacy Program in Federal Procurement of Pharmaceuticals. According to the Federal Register's Summary:

Section 703 of the National Defense Authorization Act for Fiscal Year 2008 (NDAA-08) states with respect to any prescription filled on or after the date of enactment of the NDAA, the TRICARE Retail Pharmacy Program shall be treated as an element of the DoD for purposes of procurement of drugs by Federal agencies under section 8126 of title 38, United States Code (U.S.C.), to the extent necessary to ensure pharmaceuticals paid for by the DoD that are provided by network retail pharmacies under the program to eligible covered beneficiaries are subject to the pricing standards in such section 8126. NDAA-08 was enacted on January 28, 2008. The statute requires implementing regulations. This final rule is to implement section 703 of the NDAA-08... [This final rule is effective May 26, 2009](#).

Background

If you've read the Pharma Compliance Blog for a while, you will remember that CIS Senior Compliance Manager Meredith Taylor has been tracking the DoD's progress in drafting this document, and providing answers to manufacturers confused and frustrated by the lack of guidance around processing TRICARE utilization data. For example, you wondered if you were really supposed to use Medicaid ROSI templates to process TRICARE rebates. In her April 16, 2008 [TRICARE Update: Where Oh Where is My Utilization Data?](#), Meredith confirmed that the DoD did, in fact, want manufacturers to use the ROSI templates (used to process state Medicaid rebate claims) to submit TRICARE rebate data to the federal government.

Continued on Page 4...

[HOME](#)

Continued from Page 3...

TRICARE Proposed Rule

On July 25, 2008 the DoD issued a Proposed Rule, to address the TRICARE provisions outlined in the NDAA-08 (see [TRICARE Proposed Rule](#) by Meredith and Katie Lapins, Director of Small and Mid-market Pharma). The Proposed Rule established refund procedures, and stated that:

...in the case of the failure of a manufacturer of a covered drug to make or honor an agreement to ensure that DoD pays no more than the Federal Ceiling Price (FCP) for covered drugs provided through the TRICARE Retail Pharmacy Network component of the program, the Director, TRICARE Management Activity (TMA), in addition to other actions referred to in the rule, may take any other action authorized by law. ([Federal Register Vol. 74, No. 50](#) - Section B. Provisions of the Proposed Rule)

However, many companies still struggled to format TRICARE utilization data, calculate rebates, and accrue refunds (see [Manufacturers Wrestle with TRICARE Data](#)). Now that the TRICARE Final Rule has been issued, manufacturers are hopeful that a clear-cut path to participating in the TRICARE Retail Pharmacy Program and dealing with TRICARE data has been provided.

Provisions of the TRICARE Final Rule

Section D. Provisions of the Final Rule, describes changes and additions made to the Proposed Rule, based on comments provided by the pharmaceutical industry (good work peers!) and the retail pharmacy sector (Section C. Public Comments), and additional research performed by the DoD between issuing the Proposed Rule on July 25, 2008, and issuing the Final Rule on March 17, 2009. We have included the most relevant excerpts from [Federal Register Vol. 74, No. 50](#), Section D for your review:

Like the proposed rule, the final rule adds to section 199.21 of the TRICARE regulation a new paragraph (q) regarding pricing standards for the retail pharmacy program... to state in simpler terms DoD's interpretation of the statute as requiring that all covered drug TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices under 38 U.S.C. 8126.

Paragraph (2) provides that a written agreement by a manufacturer to honor Federal Ceiling Prices in the retail pharmacy network as required by the statute is with respect to a particular covered drug a condition for inclusion of that drug on the Uniform Formulary (Tier 2) and for the availability of that drug through retail network pharmacies without preauthorization. A covered drug not under such an agreement requires preauthorization to be provided through a retail network pharmacy. This preauthorization requirement does not apply to other points of service... The final rule adds to the list of non-covered drugs for this purpose any drug provided under a prescription and dispensed by a pharmacy under the Section 340B program.

The final rule adds a new paragraph (q)(2)(iv) stating that the requirement for a manufacturer's agreement to honor FCPs in the Retail Pharmacy Network as a precondition to Uniform Formulary (Tier 2) placement may, upon the recommendation of the P&T Committee, be waived by the Director, TMA if necessary to ensure that at least one drug in the applicable drug class is included on the Uniform Formulary. Any such waiver, however, does not waive the statutory requirement that all covered TRICARE Retail Pharmacy Network prescriptions are subject to Federal Ceiling Prices; it only waives the exclusion from the Uniform Formulary of drugs not covered by agreements.

Paragraph (q)(3) addresses refund procedures. Paragraph (q)(3)(i) states that refund procedures to ensure that pharmaceuticals paid for by DoD that are provided by retail network pharmacies under the Pharmacy Benefits Program are subject to Federal Ceiling Prices shall be established. Such procedures may be established as part of the agreement referred to above, or in a separate agreement, or pursuant to section 199.11...

Paragraph (q)(3)(ii) provides that the refund procedures shall, to the extent practicable, incorporate common industry practices for implementing pricing agreements between manufacturers and large pharmacy benefit plan sponsors. The procedures will provide the manufacturer at least 70 days from the date of the submission of the TRICARE pharmaceutical utilization data needed to calculate the refund before the refund payment is due. The basis of the refund will be the difference between the average non-federal price of the drug sold by the manufacturer to wholesalers, as represented by the most recent annual non-Federal average manufacturing prices (non-FAMP) (reported to the Department of Veterans Affairs (VA)) and the corresponding FCP or, in the discretion of the manufacturer, the difference between the FCP and direct commercial contract sales prices specifically attributable to the reported TRICARE paid pharmaceuticals, determined for each applicable NDC listing. The current annual FCP and the non-FAMP on which it was based will be those applicable during the calendar year in which the prescription was filled.

As under the proposed rule, paragraph (q)(3)(iii) provides that a refund due under the law is subject to section 199.11 of the TRICARE regulation, the section that governs recovery of overpayments. The final rule provision has been revised to clarify that the refund amount will be treated, in the vernacular of section 199.11, as an erroneous payment. The final rule has also been revised to elaborate that the applicability of section 199.11 brings with it a procedure for a manufacturer to request waiver or compromise of a refund amount due under the statute. During the pendency of any request for such a waiver or compromise, a manufacturer's written agreement to honor FCPs shall be deemed to exclude the matter that is the subject of the request for waiver or compromise so that the agreement, if otherwise sufficient, will continue to be sufficient for purposes of satisfying the precondition to Uniform Formulary Tier 2 placement.

Continued on Page 5...

Continued from Page 4...

Also, during the pendency of any such request, the matter that is the subject of the request shall not be considered a failure of a manufacturer to honor an agreement for purposes of remedies for noncompliance. The final rule is further revised to state that a request for waiver may also be premised on the voluntary removal by the manufacturer in writing of a drug from coverage in the TRICARE Pharmacy Benefit Program. This change further protects a manufacturer from involuntary involvement in the program.

One other change to the refund procedures paragraph is that a new paragraph (q)(3)(iv) has been added to state that in the case of disputes by the manufacturer of the accuracy of TMA's utilization data, a refund obligation as to the amount in dispute will be deferred pending good faith efforts to resolve the dispute. If the dispute is not resolved within 60 days, the Director, TMA will issue an initial administrative decision and provide the manufacturer with opportunity to request reconsideration or appeal consistent with procedures under the TRICARE regulation. When the dispute is ultimately resolved, any refund owed relating to the amount in dispute will be subject to an interest charge consistent with the normal regulatory practice.

Paragraph (q)(4) provides that in the case of the failure of a manufacturer of a covered drug to make or honor an agreement under paragraph (q), the Director, TMA, in addition to other actions referred to in the paragraph, may take any other action authorized by law. This paragraph is unchanged from the proposed rule.

Finally, a new paragraph (q)(5) has been added. It provides that in cases in which a pharmaceutical is removed from the Uniform Formulary or designated for preauthorization, the Director, TMA may for transitional time periods determined appropriate by the Director or for particular circumstances authorize the continued availability of the pharmaceutical in the retail pharmacy network or in MTF pharmacies for some or all beneficiaries as if the pharmaceutical were still on the Uniform Formulary.

Look for an in-depth account of these changes on the Blog and in the upcoming PCX Newsletter, and feel free to contact CIS at any time to discuss how the changes might affect you and your company! We at CIS are working hard to make sure you have the tools you need to comply with the TRICARE Final Rule by its effective date of May 26, 2009!

Bill Baxter Brings Extensive Pharmaceutical Government Programs Expertise to CIS

By: Jackie O'Connor, CIS Marketing Associate

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CIS is pleased to announce the addition of new management team member, Bill Baxter. CIS is excited to have Mr. Baxter, a proven professional who will help guide the company's continued growth, specifically in the Government Programs area.

Bill Baxter has over 38 years diverse pharmaceutical industry experience including Medicaid Contracting, Government Affairs, Sales, Sales Management, and Training. Prior to his work at Johnson & Johnson, he taught social studies in the St. Louis School System.

"Many in the industry know Bill's work with the numerous federal and state programs and his vast experience and knowledge in the Medicaid market," said Chris Cobourn, VP Regulatory Compliance and Practice Lead.

"His expertise will be a valuable asset to CIS. This is especially true now with so many changes and increased scrutiny at both the Federal and State levels. Bill has been involved in Medicaid and other programs since their beginning. His well rounded understanding of the programs, including the agencies, the regulations, and the operational and organizational impact at the manufacturer, brings a unique perspective that will be a great compliment to our current staff of GP consultants, and we are very excited to have him join the CIS family."

Bill formerly held the position of Chairman of State Health Care Policy Council, an organization tasked with providing a forum for J&J operating company management to review emerging health care issues and developing policy. He was also a participating member of J&J Medicaid and Medicare Task Forces.

[HOME](#)

Letter from the Editor

Legal Documents 101

Meredith Taylor, Esq.

Dear Readers,

Lately I have been receiving many questions from colleagues and clients such as: What is the difference between a law and a regulation?, What is a Final Rule?, What is a Congressional Act?, Are statutes and laws the same thing?, What does public law mean?, When do you use case law? It is very important to know the answers to these questions, because understanding the difference between these legal documents is necessary to understanding the implications of the legal document you are reading. For example, some of the articles in this newsletter discuss the new TRICARE Final Rule, which references the National Defense Authorization Act and TRICARE regulations. Without understanding how the Act and previously published regulations affect the TRICARE Final Rule, it is almost impossible to understand the implications of the Final Rule for your company.

This article will act as a crash course in legal documents; I will explain what the documents are and describe their level of legal importance. For further reference, the PCX defines a number of these documents in the General Information Section, so when you are researching using the PCX, you can easily refer to this section to understand what type of document you are looking at and its level of importance: <http://gp.cis-pcx.com/general-info/federal-publication-procedures/>.

Acts of Congress, Statutes, Laws

A Congressional Act is a bill that has passed both the House and the Senate and has been signed by the President. It is numbered as public law (relating to the general public) or private law (relating to specific individuals or entities). An example of a Congressional Act is the Veterans Healthcare Act of 1992 (P.L. 102-585). Congressional Acts are published in the United States Statutes at Large in chronological order. The content of Congressional Acts spans various topical areas.

Congressional Acts may eventually be published in the United States Code (USCS) as a statute (aka a law), or a group of related statutes also referred to as an Act (e.g., the Public Health Services Act, the Food Drug and Cosmetic Act)).

The Law Revision Council determines whether a Congressional Act should be codified (published) in the USCS as a statute; the decision is based on whether the content is general or permanent in nature. If it (or a portion of it) is not published, the Congressional Act is still enforceable and referenced by its public law number.

The USCS is divided into 50 topical areas known as Titles. Congressional Acts may have provisions that fall into various Titles, so they will be broken up and published as separate statutes, but they may still be referenced as the original Congressional Act with the public law number (e.g., the Veterans Healthcare Act, see below).

It can become confusing because Congressional Acts published in the United States Statutes at Large (e.g., Veterans Healthcare Act) are not the same things as Acts published in the USCS (e.g., Public Health Services Act). Sections of the Veterans Healthcare Act are actually published in the USCS under the Public Health Services Acts; confused yet? The general rule of thumb is that if you see a P.L. designation, it is Congressional Act and if you see a Title number followed by USCS and a section number, it is a published Act (collection of related statutes) or statute.

Congressional Acts, statutes, and laws are all enforceable and carry the same weight; the difference lies with where they are published (Congressional Acts vs. statutes/laws) or their nomenclature (statute = law).

Regulations, Rules

Regulations are legal documents published by Federal Government Agencies to interpret and implement statutes. Federal Agencies are created and empowered by Congress, and given the power to interpret the four corners of a statute and enforce it through regulations.

Regulations are published in the Code of Federal Regulations (CFR). They are listed by topical areas, like the USCS.

Before a regulation is published in the CFR, it appears in the Federal Register in chronological order, first as a Proposed Rule. A comment period is offered to gather industry comments, the Proposed Rule is revised, and then a Final Rule is published.

The Final Rule alerts the reader to where in the CFR the Final Rule will be codified as a regulation, but this does not happen immediately. As such, the Final Rule is referenced and is cited as it appears in the Federal Register (Volume number and page number). Once the Final Rule is published in the CFR, or an existing regulation is amended by the Final Rule, citing to the Federal Register/ Final Rule referencing should cease and the actual CFR regulation should be cited.

Continued on Page 7...

Continued from Page 6...

For example, the TRICARE Final Rule was published in the Federal Register on March 17, 2009 in Volume 74, No. 50 Page 11279. This Final Rule will be incorporated into the existing regulation governing the TRICARE Pharmacy Program at 32 CFR 199.21. Once that occurs, this section should be referenced when discussing the TRICARE Pharmacy Benefits Program, but until then, it is proper to reference the Final Rule in the Federal Register.

It is important to understand that regulations have the same force and effect as law. The only time that a regulation would not be treated in this manner is if it contradicts a law. If that is the case, the regulation would likely be amended.

Legal Opinions, Case Law

Case law is developed through the judicial process. Typically, litigation ensues when two parties disagree over the interpretation of a law or regulation. If the disagreement is regarding a law, the parties prepare an argument to be heard by a civil or criminal court Judge. The Judge then renders an opinion that is published as case law. If the disagreement is regarding a regulation, the process is similar, but the arguments are heard by Administrative Law Judges and the procedure for argument is slightly different. In the end, however, an opinion is rendered and case law is developed.

In either process, the end result is a legal opinion/case law which is a binding legal precedent in the jurisdiction in which it was rendered. The case law serves as an interpretation of the statute/law under a specific set of facts, and binds all similarly situated parties.

The following is a summary of the different federal legal documents discussed above, and their publication processes.

Type of Legal Document	Published By	Branch of Government	Publication
Congressional Act	Congress	Legislative	United States Code
Statute	Congress	Legislative	United States Code
Regulation	Agency	Legislative/Executive	Code of Federal Regulations
Rules (Final, Interim, Proposed)	Agency	Legislative/Executive	Federal Register
Case Law	Judicial	Judicial	Federal Reporters

I have provided you with a summary of some federal legal documents. States operate in the same way, with minor differences from state to state; the same logic and document interpretation applies.

Please feel free to contact me at anytime if you have any questions about legal documents, their differences, and/or their binding effect.

Best regards,

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[HOME](#)