

Regulations! Regulations! Read All About It: Insights Into the Regulatory Process

Please stand by for real-time captions.

Good afternoon and welcome to the Academy webinar regulations, Regulations! Regulations! Read All About It: Insights Into the Regulatory Process . This is Kathy Carmichael and we are here today centers Tonya flash [Indiscernible - static] clinical science, global affairs and government information at Yale University and Jennifer Castle reference documents library [Indiscernible - static] University. Before we get started I will go through our housekeeping reminders. If you have any questions you would like to ask the presenters, or if you have any technical issues, please feel free to use the chat box and for people in desktop computers or laptops is located at the bottom right-hand corner of your screen. I will keep track of all the questions that come in and at the end of the presentation Tonya and Jennifer will respond to each of them. We are recording today's session. And we will email a link to the recording and slides to everyone who is registered for this webinar. We will also be sending certificate of participation using the email you used to register for today's webinar and if anyone needs additional certificates because multiple people are watching, with you, please email FPL see outreach at GPO.gov [Indiscernible - static] email addresses [Indiscernible - low volume]

Desktop computer or laptop computers [Indiscernible - static] on these lights being presented and click on the dual screen button at the bottom left-hand of your screen and to exit the full-screen mode mouse over the blue bar at the top of your screen so it expands. Click on the return button to get back to the default view. At the end of the session we will be sharing webinar satisfaction survey with you. Will let you know when the survey is available in the URL will appear in the chat box. We would very much appreciate your feedback after this session including comments on the presentation style and the value of the webinar. Finally objects presenters will be sharing screen sharing the presentation today which means once they start talking you will no longer be able to see the chat box. If you want to ask a question or just want to watch the chat traffic as they are presenting, once the screen sharing begins mouse over the blue bar at the top and when the menu drops down click on the chat to enable the chat box. [Indiscernible - static] let us get started.

Thank you, Kathy, hello and welcome everyone and thank you for coming to our webinar on regulations my name is Jennifer Castle from Tennessee State University and my colleague is Tonya flash from Yale University. A little bit before we begin, the regulatory process can be complicated and a bit convoluted so we want to be clear that a comprehensive [Indiscernible - static] process is something that would likely require a series possibly a series of webinars so we simply cannot cover everything today. Further we are not experts and we are only providing a basic overview of the process and where to locate resources. Unfortunately the base lights for [Indiscernible - static] in the ESD or or much more user-friendly website that they watched last week and we will touch on those in a bit. So today we will cover key concepts and ideas in regulatory process and where to find resources. So to begin these are some important concepts and ideas we felt were pertinent to the regulatory process. A regulation is an authoritative rule giving details and procedures after congressional bills become law, federal agencies that are

responsible for putting those bills into action through regulation. The role is a prescribed guide for conduct and the unified agenda is a semi annual compilation about regulations under development agencies.

The Federal Register is a daily publication of that U.S. federal government that issues proposed and final administrative regulations of federal agencies. Additionally this publication includes executive orders and other presidential documents. Federal Register documents is a term used to encompass all documents published in the Federal Register and these include notes, proposed rules, rules, and in some cases other documents. So I for the office of information and regulatory affairs as a federal office the Congress established in the 1980 paperwork reduction act. In addition to reviewing government collections of information from the public under the paperwork reduction act, Ira reviews draft supports and final regulations under Executive Order 12 8 66 and developed an oversee the implementation of governmentwide policies in the areas of information policy, privacy and statistical policy. Ira also oversees agency implementation of the information quality act to include peer-reviewed practices of the agency. The Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the department and agencies of the federal government. Just as a note the online CFR is a joint project authorized by the publisher the national archives and records administration and office of the Federal Register and GPO to provide the public enhance access to government information and it is unofficial. Regulation.gov is your source for information on the development of federal regulations and other related documents issued by the government. Through this site you can find, read and comment on the regulatory issues that are important to you. And finally rake map is an overview of the informal rulemaking process and most regulations follow these steps and exceptions include the requirement by the administrative procedures act, [Indiscernible - low volume] type or formal rulemaking in certain situations or specific details and legislation on how to promulgate the rule. And I will let Tonya take it from here.

So the administrative procedure act of 1942, this act public law 79 section 404 [Indiscernible - static] statute 277 was enacted in June 11 1946. This act is a federal statute that governs the way in which administrative agencies of the federal government propose and establish regulations and grants and you was federal courts of oversight over all agency actions. And so this is a really key act and what we will be discussing today. So if you want to know more about these backgrounds, what regulations are passed as they are, you will want to look into the administrative signature packed. Executive Order 1286 already heard this from Jennifer and this was passed October 4, 1993. By Bill Clinton. It provides the significant regulatory action have to be reviewed by the office of information and regulatory affairs or Ira. A significant regulatory action is one that would have a huge impact on the economy, or would affect other agencies , may cause additional legal issues, all of these final changes that go through this process that causes significant regulatory actions need to be reviewed by the OMB. Another Executive Order is that really impacts the process that we will talk about in a few minutes. It is Executive Order 13 566 and this is called the improving regulation revelatory review and this is issued by President Barack Obama in 2011 and it encourages agencies to coordinate the revelatory activities and to consider regulatory approaches [Indiscernible - static] of regulation while also

maintaining flexibility and freedom and choice for the public. It directs agencies where feasible and appropriate to seek the views of those likely to be affected by the proposed rulemaking before a notice of proposed rulemaking is issued. And so these two executive orders and these administrative procedure act are going to be key to understanding the informal rulemaking process. Next slide, to understand the steps of formal rulemaking I've provided this map with linkages at the bottom to explain what is happening through this process. Just a qualified, formal rulemaking generally occurs when a statute outlines what process a rule takes. But if a statute hasn't said this is how a rule will be promulgated, then this map, I will break it down in the next few slides, will discuss the process that most agencies regularly follow. It is generally informal rulemaking. And so overall, there are going to be nine steps. First you will consider the initiating event. This is a long Congress -- is it a court decision? Are these agency initiatives? The different way in which that initiative event occurs may impact the way the things that the rule needs to go through before it becomes or before it ends the process. Specifically is there a need for a public notice? That leads us to the second step, is there a need for a public notice? Well unless it is identified in the administrative procedure act, section 553, that there is a good cause for any other exemption, there is generally a need for public notice. The third step, so in this step you will need to develop a proposed rule. As laid out in the first title of the CFR, section 18, chapter 18 section 12, a notice of proposed rulemaking must have a legal basis, post provision and rationale. The preamble must have a regulatory history and background, alternatives agencies are considering and initiatives of legal analysis. That may occur. In addition, setting up step three, there legal analysis that the rulemaking procedure may need to go through that will continue until step seven. So step three through step seven are generally aware and Executive Order 12866 [Indiscernible - static] 12866, Executive Order 13563, regulatory flexibility act and the paperwork reduction act as well as other types of analyses are completed. So after we developed this proposed rule, it then got sent to the office of management and budget form and literally known as the OMB and other agencies for review so went it is sent to the OMB there is first the 10 day review by the OMB to analyze whether they meet that significant determination I just talk about earlier. Our third [Indiscernible - static] also has to go through a 90 day OMB review. For assessment, analysis, including some of those legal analysis. So there are times when there may be extension granted and if an extension is granted, it means from 90 days to 120 days. Finally, I may also waiver review for that rule. Step five, there needs to be a notice published a notice published of the public rulemaking and this must include the time, place, nature of the public rulemaking procedure and it must reference legal authority and it must have a regulation identification number. Or are I am. The agency must also analyze public comments. Agencies must provide responses to significant issues raised in comments after which after they have gone through analyzing the comments, we can then go ahead to develop the final rule incorporating some of the feedback from the other steps we have gone through. The final rule must explain any adopted provisions, must respond to public comment and must update and finalize analysis that began in step three, and must have an effective date for the compliance phase. That we will send the final rule to the OMB for review. The rulemaking schedule must include the 90 day OMB review period. After which the final review will be published. Most final reviews are not going to affect until 30 days after publication and the final register. So house, Senate and the government accountability office must review the federal review before it can take place between 30 and 60 days.

Thank you, Kenya. [Indiscernible - static] complicated [Indiscernible - static] but we hope that these resources that we will touch on today will help you understand a little bit better about what we are discussing. And so some of these with these four websites we will touch on some of the important information that you can find there and again I want to stress this is not brands of. It is just to provide a respective idea of the respective functions and Kenya will be posted the links in the chat so these web resources are Unified agenda , regulations.gov, Federal Register, and Elik Tronic Code of Federal Regulations. So we are unsure how long this will run, so you have any questions we suggest you put them in the chat and hopefully you will have a chance to have a sent to them at the end, to begin, Unified agenda is published in the spring and fall of each year, it identifies regulatory priorities and [Indiscernible - static] actions in the next year. Essentially regulations.gov provide the document to plan that agencies have four regulations in the short and long-term. On the Unified Agenda website , you can look up current and historic unified agendas as well as regulatory plans, completed actions, inactive actions that you can view rules and [Indiscernible - static] six regulatory review and those that have concluded in the past three days, in addition to public comment only on the OMB recommendation for a new Executive Order on regulatory review. So looking at this page this is a screenshot for the bottom of the page and other know if you can see my pointer or not, it has a scrolling box for what is new, the reason of why it is included in this box is because the other boxes [Indiscernible - static] along in the tab, in the tabs along the top so there is a little bit of a redundancy in the design of the website, but it is probably useful for folks who haven't visited Reginfo.gov before.

The great thing about this site is the ICR dashboard which can be selected under the information collection review tab. It provides these handy-dandy graphs that help visualize regulatory actions within various agencies and pending actions by rule states which can be found using the ICR dashboard [Indiscernible - static] and clicking at the tab at the top. While the graphs are on the home page, I really do suggest you actually go to the dashboard because you can review more information there as it will explain. Back one more.

Thanks. On the dashboard for this example I have selected the Department of Health and Human Services. Which as of last week had the most selections under review at 144, what is something that you could [Indiscernible - static] pie chart to do that because it is a screenshot but by viewing by type, which is a little drop-down box here at the bottom, you can select by type obviously by reviewing and by rulemaking and under these visual elements are links to the various review types by revision for the respective agencies selected so for this it also has health and human services, there you'll find the OMB control numbers and titles and the types in the dates they were received in their current expiration dates and so on for review. I think this helps the [Indiscernible - static] process and [Indiscernible - static] information collection review process, it is explained in the frequently asked questions page on the site. So now we will look at the Unified Agenda. You just simply click it at the top, the tab at the top. To fit it into this light I provided the screenshot of where to search for the spring 2020 agenda. To search it simply a drop-down menu where you select by agency and it provides the rules list. The one you selected, it is also under the Unified Agenda tab and there are historical Unified Agenda

regulatory plans. So to search historical unified search and [Indiscernible - static] [Indiscernible - low volume] in the fall and spring so for this one I selected spring 2020 and from here you can look at the plans and long-term actions for consistency, and next slide, I select Department of Health and Human Services. And here is the agency for the spring 2020. You can see where each rule is in the agenda. State of rulemaking, and respective rule identification numbers. And from there you can select the rule and raise an abstract. And this really touches on the really most important part of Reginfo.gov to get you started. So moving to regulations.gov, the essential flex function of regulations.gov is an online commenting platform for rules and regulations and serves to engage the public the public access to regulatory materials and increase rulemaking participation. In the Federal Register you will find proposed rules, public notices, notices of proposed rulemaking, final rules, which are for regulations, executive orders proclamations and other presidential documents. Regulations.gov give us a method in which our voices could be heard on rules and notices on rules. So as I mentioned before earlier when we got started regulations.gov just launched a beta site and this is what it looks like before so some of you may recognize it if you do any central regulations. But as of July 31st, this is the beta site. The biggest difference between old and the beta site is an optimized search engine. With the most \$10 million on regulations.gov, we are turning meaningful [Indiscernible - static] necessary for the public to participate in the rulemaking process. Additionally search results are divided into dockets, documents and comments. And the basis site is not used in [Indiscernible - low volume] devices. With the new search engine you can find a proposed rule, notice, or rule on regulations.gov by entering a keyword, title or if you have the document, a deed, you can put it on the search area in the home page and click the search button. Search results will display on the document browser tab what you can never your results with filters on the screen. Once you find the relation of interest, click it [Indiscernible - low volume] details page. Also seen on the old site, there is a trending section in an area where you could access dockets in which comments are due to close soon which is over here on the left-hand side of the page. You can tell by the icon under these two words is trending, there are little icons in each of the upper left-hand corner's here to indicate whether it is a proposed rule or rule or notice . When I took the screenshot there were not any rules in the trending area but it is green just for your information. They also made it easier to [Indiscernible - static] improve the website that is there on the bottom left. Truth be told, there is not much difference between the old and the new [Indiscernible - static] apart from this up to my search engine but it is definitely clearer and more visually appealing. So for example say if you were to select today, it would take you to a list of documents on the docket, excuse me. You can refine the search by age of agency which is down here on the left. At the bottom. And it is very similar to database searching. What I feel is important for you to see is what those individual documents look like. This is an example of a rule. You can see by the green icon here in the upper right corner, and they will always tell you when the comment section will and in the upper left-hand corner. It also provides the Federal Register number, Code of Federal Regulations citation that is applicable to the document, and abstract, those are all going to be found on the left-hand side. What subjects and topics the documents fall under, for example this rule is having topics of accounting and administrative top -- practices, education, grant program etc. And that even [Indiscernible - static] further defined the document and also could be found here on the left-hand side and also will tell in the document when was it received in the date comments were opened up to the comment.

You can also browse the comment section which you can see instead of appear on the top, and you can then leave a comment of your own. So this is basically the comments page and what it looks like, and of above the top is where you leave your comment. Plus you can also upload supporting documents. You can opt to receive email confirmation upon submission and receive a tracking number. And it gives you the option to comment as an individual, as an organization, like a company or government entity, or anonymously. Further down the page at the bottom, we have implemented a recapture which I'm sure you have encountered indicating that you are not a robot and to prevent actual bots from flooding the comments.

That is basically covering the vital points of regulation.gov and I will turn it over to Kenya to discuss the Federal Register.

Thank you, Jennifer. The Federal Register is a daily compilation of rules and regulations and more. Of the United States government. It's to back number is 82.106 and there is online access to the Federal Register as a way back to 1936 [Indiscernible - static].gov. Jennifer will provide that link.

The Federal Register site through the national archives are very easy to use. One has access to the current issue of the federal register, the previous of the next days Federal Register also known as the public inspection, and the ability to search in a variety of ways. So something I want to.out on this site, to search historically all the way back to 1994, you would just use the search bar here additionally it does.out that you could find older documents on regulations.gov and you can also use the date feature [Indiscernible - static] sorry, moving onto the next slide, to search by section, you can easily look at the top of the page in your drop-down and the thing I like about this is it begins certain topical areas for which you can find that they regulation or you could find the public section from the day before.

You can use that or you could scroll to the bottom of the page and you can always get a portion of the picture and it will also break up into the same title.

To search by agency, or by topics that use Code of Federal Regulations indexing terms, they are by date, by public inspection, and, or by presidential documents and then title III information, you can use the bell feature at the top of the pages. A bit more about presidential documents. You are able to search executive orders, proclamations, statements, and more, by the administration. And that is something that I think would be very useful when you're working with your [Indiscernible - static]

One [Indiscernible - static] issue of federal regulations, you are going to yes, you will want to ensure you have the correct date by looking at the top page, top of the page, as you can see by the arrow indicated, or to the right hand side which will indicate what date you are on. You may also want to have a look at the entire document if you look at the hour that is on the right-hand side that says download picture to the PDF and that will download the entire copy of the Federal Register for that date. And what makes that date useful is that you can do the control,

the command F, to search for specific topics within that document. If you're not sure how it is coded with any issue itself or to the table of contents.

You may also [Indiscernible - static] as a reminder [Indiscernible - static] sorry, you may also want to look by department for which agency is looking for rules and so you can scroll through the table of contents for that information as well.

Now that we have discussed the Federal Register let us talk a little bit about the Code of Federal Regulations. As a reminder the Code of Federal Regulations is a codification of the general and permanent rules that established by the federal -- establish in the Federal Register, by the department and agencies of the federal government. It is Reckitt nice by subject. As opposed to by date and the Federal Register. The subject breakdown is known as title. The printing regulation of the Code of Federal Regulations is the official copy, while the electronic copy or as we will call it the E-CFR is unofficial. The online CFR is a joint project authorized by the national archives and records administration office of official -- office of the Federal Register and took one. The sea.number for the CFR is 88 2.1 06 slashed three.

So the image here is a copy of one of the titles within the Code of Federal Regulations. It is printed periodically and changes to the print CFR will often be found in the Federal Register or in the list of the CFR section section -- which could be found in the link that Jennifer is going to paste in the chat. As the updating mechanism takes a while to process, we are not going to focus on the print CFR. Instead we will focus on the E-CFR which is unofficial provide the most up-to-date information on changes to the CFR. So the image here depicts the current E-CFR site. As you can tell, you are able to browse the site on the left-hand side or in the drop-down menu, or you can search topically or use an advanced search. But unless you have an in depth [Indiscernible - static] challenging to search. And so for this reason we decided to focus on the new beta version of the E-CFR for the rest of the presentation. So one of the things that is really great about the new beta version is that it is much simpler to use. At the top of the page, you can see you can be in search of her title and concert with regular search and you can look at any recent changes that have been made to the Code of Federal Regulations. And you can look for any corrections that have been made. The current page also provides a link that explains how often the E-CFR is updated and that is right there but the editorial process there. And it also -- encourages you to learn more about the email subscription which allows you to subscribe either by email or to our SFP.

Further down on the first page you are able to search other attestations [Indiscernible - static] first arrow or you are able to click through the titles to see if they are exactly what you need. Or you can view recent changes. Want to click through a title, you can then determine what section of the title to explore using either the timeline, off on the left-hand side, or you can go to the date, specific date, or you can search within that title for whatever you are looking for. Good to know, those who are looking to see what the history of a certain part or section or subchapter of the CFR, what that history is, not able to use the hierarchical format. You would need to use the search for these features to get to the specific area you are looking for and then you can use the title. That is a very quick overview of many of those things in the CFR and

the e-CFR, I want to thank you for your attention to our description and I am going to pass it to Jennifer.

Thank you, Kenya, we know we just covered a tremendous amount of information. Like we mentioned before, federal regulations on the researchers are really a series of [Indiscernible - static] what we did try to do is address many of the questions that were submitted one folks registered for this webinar. And so we just were not able to get to all of them. However, we are happy to answer any questions that you might have right now, so Kathy?

Do you have any questions for us?

[Indiscernible - low volume]

This is Kathy. There was one, Emily Hickey asked, please review step nine.

That that makes sense?

Yes. For the step nine, I met that I would go over it -- Emily, 82.1063, that is just -- you see that number. Just in case you are trying to figure out for the CFR.

I hope that answers your question going back -- so the final rule, [Indiscernible - static] final rule [Indiscernible - static] after going through, pending the following for review, then it is published. However, the details that I highlighted is that the final rules cannot go into effect until 30 days after publication in the federal level register. The health and Senate and GPO must review -- and the GAO must review that final rule before it could take effect in that amount of time, 30-60 days. Okay, Emily, I see that -- apparently I am not -- it is not coming through clearly. I was just seen that.

Okay. [Indiscernible - static] you cleared that up for her. Are there any more questions?

Okay, Emily, you asking out a specific [Indiscernible - static]

So a see dock is a shortened version of a superintendent document which is the arrangement of government documents. So the C.is how a document is arranged within that system. I will find a link, just one moment.

Yes, Emily, it is something that is not always use and this is Kathy, other libraries use a Library of Congress, or some even use Dewey decimal, just depends -- each library decides which classification system that it uses. For itself. GPO does not to take that.

Okay, that will give you more information. Are there any other questions about regulations on the webinar?

If I can say something, Kathy, I do want to encourage people to check out those beta sites. You get the chance to comment or discuss how this would be used in a practice. Specifically for the e-CFR, because some of the questions you are asked is how can we find them in there in with the way that it is out now, it is much easier to navigate to the topics you are looking for. And the code of regulation. Than to just guess what is available.

Hold on just one second. Okay. I am waiting for a response for someone, but can you go ahead and push out the survey link and if you do not catch the survey link this time, we will also paste it out with the link to the recording. We really would like if you can, everyone to respond, because we do take your suggestions seriously. Some of the webinars, in fact this whole series, was actually a suggestion from STL.

So I see that Joe has a question about do updates to rules go to the federal review process? And Joe, I really think it depends on how those updates -- how those updates were put into place. Often -- that is one of the beauties of looking through the Unified Agenda, so if there is a rule that has been there and there is a dramatic change that would need to happen, that I believe it would have to go through that federal review process. But there are times when there are other workarounds that regulations go through and agencies, I believe, will post to their website that there is a rule change. That is happening.

Okay, Kenya and Jennifer, can you talk more about setting up awards for regulations?

Yes, give me a second, one moment.

Okay.

We have plenty of time left so that is fine.

Just to be clear, when you say do you mean awards from regulations.gov? Where it is alerts -- where your comments are coming through? And that kind of process? Or do you mean alerts from the Federal Register?

Just for clarification.

Okay, both.

And so I am going to -- Federal Register, we will start to there. You can subscribe to the are is F, but it also allows for email notification. So what you would need to do is look for a light orange subscribe button with RSF and orange symbols to the right of the page. That is the request, can you see that? I don't know , and I am going to say that is something that I can look to see if that happened. I am going to say chances are there haven't been. [Indiscernible - static] but I [Indiscernible - static] does not [Indiscernible - low volume] CFR. And because most things have been shut down, I don't [Laughter] --

Phyllis, similar from outreach can actually look into that for you and I believe we just got a list of publication statuses, so I will try to get back to you later this week on that.

All right, do we have any other questions?

Kenya, and Jennifer have added their contact information so if you think of something later, I am sure they would be happy to respond.

Yes, of course, if you have any questions, we would be happy to answer any inquiries and you have my email. [Indiscernible - static] any questions [Indiscernible - static]

It is a lot of process.

[Indiscernible - static] has sent a link, [Indiscernible - static] bookstore and he has a link to the bookstore and the CFR.

James, you say e-CFR is the kind of CFR ? Yes, yes, it is. The e-CFR is the most up-to-date CFR plus any final rules.

Jim is asking what is your favorite commercial for searching the CFR [Indiscernible - static] West wall -- Westlaw?

Yes,.

I prefer time of line. Bias but I just like the platform and I like the ability to search -- it feels like it is more of a broad search [Indiscernible - low volume] so that is my bias.

Okay. One last call for questions.

I am waiting for that so I will say thank you very much to Kenya Flash and Jennifer Castle for doing this webinar today and I know this is one of the most requested topics and I appreciate them participating and get this flowing and the series and speaking of which for next webinar it will be September 15, on government citation. And then we will have coming up team resources and then I am already looking on webinar for [Indiscernible - static]

We want to thank you, Kathy NJPL for giving us the opportunity to discuss the process with everyone and is been an honor enjoyed to be together and we want to thank everybody for attending and grateful you took the time to listen to us [Indiscernible - static] admittedly intimidating so we will [Indiscernible - static] you have a wonderful day.

Yes, thank you everyone, have a great day.

Yes, thank you, everyone. [Event Concluded]