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Divided We Stand: An Update on NCR's Efforts to Secure the Divisibility Defense

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NCR's quest for divisibility at the Fox River site continues, and in the latest iteration, the U.S. District Court for the Eastern District of Wisconsin flip-flopped to find NCR had not established a basis for divisibility after all. In granting several motions to reconsider its May 2015 decision, the court determined NCR's evidence justifying the apportionment was unreliable.[1] This was a reversal of the court's May 2015 opinion in which it had held NCR had successfully established its divisibility defense to the joint and several liability it faced for CERCLA response costs.[2]

I. Background

Courts have long grappled with balancing the joint and several liability traditionally imposed under CERCLA against the basic legal principle that liability for divisible harms should be apportioned among the defendants. Most notably, in *Burlington Northern and Sante Fe Railway Company v. United States*, the Supreme Court held that when a PRP presents facts that adequately demonstrate a reasonable basis for apportionment, the PRP's liability is divisible.[3] The Supreme Court upheld various courts of appeals that had previously invoked the Restatement (Second) of Torts, which provides that apportionment is proper when "there is a reasonable basis for determining the contribution of each cause to a single harm."[4] The issue before the Supreme Court in *Burlington Northern* was whether there was a reasonable basis for that apportionment.[5] The Ninth Circuit had previously held Burlington Northern's basis for apportionment lacked sufficient precision.[6] The Supreme Court, however, rejected the Ninth Circuit's reasoning, and opted for the district court's decision which found there was a reasonable basis for the apportionment, further noting it did not require exact precision.[7]

The framework for analysis that emerged from *Burlington Northern* is a two part test that both the Eastern District of Wisconsin and the Seventh Circuit have used to determine whether the harm for which NCR is liable is, in fact, divisible: (1) whether the harm is theoretically capable of apportionment, and (2) whether there is a reasonable basis for apportionment.[8]

II. NCR's Efforts to Show Divisibility of Harm

NCR is one of multiple PRPs that have been subject to EPA enforcement action due to its role in contributing PCBs to the Fox River.[9] NCR has been attempting to establish a divisibility defense with respect to one portion of the Fox River where remediation is ongoing.[10] These efforts were not fruitful until the Seventh Circuit modified the paradigm.

In September 2014, the Seventh Circuit remanded the case to the District Court to reconsider NCR's divisibility defense with a new definition of the harm at issue.[11] Up until that point, the courts had defined the harm in terms of whether remedial action was necessary or not.[12] In other words, a remedy was necessary once the harm passed a certain threshold, so there was no reasonable way of apportioning that because "NCR failed to refute the proposition that its discharges were sufficient by themselves to cause contamination requiring remediation."[13]

In its September 2014 opinion, the Seventh Circuit changed the course when it decided that defining the harm in terms of whether the remediation is necessary is inconsistent with the continuous nature of the contamination.[14] This determination arose from a better understanding of EPA's remedial goals for the site, what constitutes a threat to human health and the environment, and how these threats will be handled depending on the concentration of the contamination.[15] Thus the Seventh Circuit redefined the harm at issue as the toxicity or the "harm to human health and the environment."[16] In redefining the harm in terms of toxicity, the question of whether the harm is theoretically capable of apportionment can be answered positively if NCR can show how much it "contribute[d] to the contamination, or toxicity, in [the site]."[17] The Seventh Circuit suggested the harm could, theoretically, be apportioned because it was no longer a question of whether or not certain discharges required remediation.[18]

In May 2015, the District Court issued an opinion pursuant to the remand.[19] The District Court revisited the Seventh Circuit's determination that the contamination was theoretically capable of apportionment, and identified what it deemed to be reliable testimony from an expert witness who provided the "percentage of the toxicity [at the site] that was caused by [NCR's] discharges."[20] The expert provided "best estimates" of volumetric contribution by each PRP and the District Court reasoned that was sufficient to show the harm is theoretically divisible.[21]

The Seventh Circuit had further instructed that if NCR could show how much it contributed, then "a reasonable basis for apportionment could be found in the remediation costs necessitated by each party."[22] Thus, NCR only needed to "demonstrate a reasonable estimate of the extent to which its contribution to the contamination [at the site] gave rise to the remediation costs incurred."[23] Following *Burlington Northern* and the Seventh Circuit, the District Court held that the same percentage of contribution NCR is tagged with can also be a reasonable basis for apportioning the amount of remediation costs for which it is responsible.[24] Thus, the District Court found NCR established its divisibility defense, and that NCR's percentage of the total cleanup costs is equal to the percentage of contamination it contributed.[25]

In October 2015, the District Court granted multiple motions to reconsider its earlier opinion, and it reversed its decision with respect to NCR's divisibility defense.[26] The District Court granted the reconsideration because it determined the evidence of volumetric contribution, provided by an expert witness, was not reliable.[27] Basically, the District Court had been under the impression that the estimates provided by this expert were conservative and that they were *not* favorable for NCR.[28] However, it turned out that there is significant evidence that these estimates were *not* conservative, and that they *were*, in fact, favorable to NCR.[29] The District Court had previously recognized the estimates of volumetric contribution by each PRP were not precise, and it acknowledged the uncertainties tied to the estimates were "by their nature, the kinds of issues that would bedevil the divisibility question in any river with multiple PRPs and an imperfect historical record."[30] However, it appears that to the extent the estimates were not necessarily precise, the District Court was striking a balance by ensuring the party seeking the defense did not benefit from the lack of precision.[31] When it determined the imprecision in the estimates of volumetric contribution favored the party seeking apportionment, the District Court found the estimates unreliable.[32] Thus, the District Court held that NCR has not provided reliable volumetric contributions by each party which could serve as a reasonable basis for apportioning the remediation costs.[33]

III. Where NCR is Headed Now

As of the date this article was written, the District Court has denied NCR's motion for reconsideration of its reconsideration, but in response to NCR's alternative request that the court certify its request for interlocutory appeal, the District Court has invited the parties to brief the question of whether the ruling on NCR's divisibility defense should be certified.[34]

IV. Implications For The Eleventh Circuit

The Eleventh Circuit has not yet addressed the divisibility defense directly. This vacuum in the case law makes it difficult for a PRP to predict its likelihood of success in establishing the defense and complicates its strategic response to enforcement actions. This is especially true in the Eleventh Circuit (and most others), where a PRP cannot bring a claim for cost recovery if it has a claim for contribution.[35] Consider a scenario where the EPA brings an enforcement action against X and Y for the same site. X enters a consent decree, and as a result X has contribution protection pursuant to §113. Meanwhile, Y thinks the EPA is asking for it to pay for more than its fair share. Y cannot seek contribution from X under §113 because X has contribution protection. Y also cannot bring a claim for cost recovery under §107 against X because Y's claim is technically a §113 claim. In this situation, Y's only option is to assert the divisibility defense against the EPA's enforcement action.

Thus, while we are not entirely sure how the Eleventh Circuit will construe *Burlington Northern* when faced with the question of whether a PRP has established its divisibility defense, we do know that the vitality of the divisibility defense is imperative for certain PRPs in this circuit.

(Endnotes)

1 *U.S., et al. v. NCR Corp, et al.*, No. 10-C-910, 2015 WL 6142993, at *1 (E.D. Wis. Oct. 19, 2015).
2 *U.S. v. NCR Corp., et al.*, No. 10-C-901, 2015 WL 2350063, at *1 (E.D. Wis. May 15, 2015).
3 *Burlington Northern and Sante Fe Railway Company v. United States*, 556 U.S. 599, 617 (2009).
4 *Id.* at 614.
5 *Id.* at 615.

6 *Id*. at 617.
7 *Id.* at 618; Bradley Marten, *Has the BNSF Case Changed the Superfund Practice?*, Marten Law PLLC, (Jan. 28, 2010), www.martenlaw.com/newsletter/20100128-bnsf-case-superfund-practice.
8 *Burlington Northern*, 556 U.S. at 615; *U.S. v. P.H. Gladfelter Co.*, 768 F.3d 662, 678 (7th Cir. 2014); *U.S., et al. v. NCR Corp., et al.*, No. 10-C-901, 2015 WL 6142993, at *1-2 (E.D. Wis. Oct. 19, 2015).
9 *U.S. v. P.H. Gladfelter Co.*, 768 F.3d at 667.
10 *Id*. at 675.
11 *Id*. at 682.
12 *Id*. at 676.
13 *Id.*
14 *Id.*
15 *Id*. at 676-677.
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17 *Id.*
18 *Id*.
19 *Id.* at 1.
20 *Id.* at 6.
21 *Id*. at 13.
22 *Id*. at 4.
23 *Id.* at 13
24 *Id.* at 16.
25 *Id*.
26 *U.S., et al. v. NCR Corp, et al.*, No. 10-C-910, 2015 WL 6142993, at *1 (E.D. Wis. Oct. 19, 2015)
27 *Id*. at 4.
28 *Id*. at 3
29 *Id.*
30 *U.S. v. NCR Corp., et al.*, No. 10-C-901, 2015 WL 2350063, at *8 (E.D. Wis. May 15, 2015).
31 *Id*.
32 *Id*. at 4.
33 *Id.*
34 *U.S. v. NCR Corp., et al.*, No. 10–C–910, 2015 WL 6912545, at *1 (E.D. Wis. Nov. 9, 2015)
35 *Solutia, Inc. v. McWane, Inc., et al.*, 672 F.3d 1230, 1237 (11th Cir. 2012).

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Two Years On From The Publication of ASTM's Phase I Standard – Confusion Reigns

By Nathan Burnside, Director of Risk Management, AEI Consultants, Inc.

In an effort to improve the consistency and quality of Phase I Environmental Site Assessments (ESA), in November of 2013 ASTM International published Standard E1527-13 (2013 Standard) which updated industry guidelines for conducting due diligence ESAs.[1] The 2013 Standard introduced or refined various concepts by, among other things:

- Establishing the importance of file reviews by requiring consultants to justify when an otherwise appropriate review is not conducted;
- Updating the definition of Recognized Environmental Condition (REC) and Historical REC (HREC); and
- Introducing the new term 'Controlled REC' (CREC) to the environmental lexicon, where a known release has been granted regulatory closure but contamination was allowed to remain in the subsurface subject to certain controls.

The 2013 Standard was also designed to more accurately reflect recent thinking on what kinds of risk are prevalent in commercial transactions, and to continue representing 'All Appropriate Inquiry' under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). It did this by adding vapor to the list of physical states by which contaminants could migrate between and among real estate.[2]

In contrast to the lofty goals of the 2013 Standard, the above changes have arguably led to increased confusion and inconsistency across the environmental consulting spectrum, particularly with regard to vapor migration. According to an Environmental Data Resources, Inc. survey, prior to implementation of the 2013 Standard vapor migration had been considered by at most 22 percent of the environmental consulting industry to be a concern worthy of recommending further action.[3] With the publication of the 2013 Standard, environmental consultants were suddenly mandated to consider the potential risks posed by vapor migration which, in effect, forced more than three-quarters of the industry to suddenly alter their approach to risk identification.

Why Vapor Is A Unique Problem

Consultants, and those who follow their reports, have traditionally been raised to believe that down-gradient contaminated sites pose minimal risk. After all, groundwater (which historically represented the biggest risk from off-site contaminated properties) usually follows site topography and rarely, if ever, defies gravity. This is plainly not so in the vapor context. Volatile gases easily diffuse through substrates following the path of least resistance on their journey to the surface.

Because of vapor considerations many down-gradient sites have now been identified to pose some risk to commercial property. By way of example, several years ago (before publication of the 2013 Standard) a groundwater and vapor investigation of a commercial package store was initiated because it was inconveniently 'sandwiched' between two gasoline stations with past releases. Surprisingly, the vapor investigation revealed high levels of trichloroethylene (TCE) and related chlorinated solvents in soil gas which are not traditionally associated with gasoline stations. More puzzling was the lack of historic operations, either at the target site or the adjoining sites, consistent with the use of these contaminants. It was finally determined that an adjacent apartment complex, located across a four-lane highway, was the likely source of the vapors because it had historically operated as an automotive dealership. More interesting was that the site was considered well down-gradient of the target property and so wasn't initially seen as a risk to the transaction.

The above investigation did not determine if vapor were actually intruding into the package store or if they were present at actionable levels. Indeed, the concept of vapor intrusion is separate and distinct under the 2013 Standard. Nonetheless, the presence of these vapors in soil gas at this site is emblematic of a problem that, several years prior, did not conform to the traditional view of what constitutes an off-site concern.

EPA's New Vapor Intrusion Guidelines Provide Some Insight For Phase I Consultants

Perhaps witnessing the confusion instigated by the 2013 Standard and sensing an opportunity to complete a project more than twelve years in the making, the U.S. Environmental Protection Agency (EPA) has attempted to ease the burden on those investigating vapor concerns at contaminated sites. In June 2015, the EPA published finalized versions of two vapor intrusion investigation guidelines, one involving the performance of petroleum vapor intrusion (PVI) assessments from underground storage tank (UST) sites,[4] and the other for

vapor intrusion risks associated with other types of sites and/or non-petroleum constituents (VI Guideline).[5]

Much has already been written about the EPA's new guidelines in both the technical and legal community. The focus of these articles has generally been on what kind of impact vapor considerations will have on transactions, as well as how legal claims will be affected. Rather than rehash these well-considered points, it may be more illustrative to point out that the guidelines, while undoubtedly aimed more at those conducting comprehensive vapor investigations, nevertheless illuminate what the 'good consultant' should do when initially assessing the risk posed by vapor contaminants.

Both the PVI and the VI Guidelines outline procedures consultants should use in planning their vapor investigations. These procedures include characterization, modeling, delineation (both lateral and vertical), evaluating vapor sources and attenuation factors, and possible mitigation, as appropriate. It is at the initial stage of this assessment that consultants should look for guidance on what constitutes a vapor concern during the ESA process.

For instance, the VI Guideline suggests collecting historical information on both the subject property and surrounding sites to establish the current and/or historical use of chemicals. Conveniently this is something that consultants already do given that historical research is a key component of environment due diligence.

Another suggestion of the VI Guideline involves determining if there is a subsurface source of vapor-forming chemicals. This would traditionally be achieved by reference to state and federal release databases coupled with detailed governmental file review (something also addressed by the 2013 Standard's mandate to conduct file reviews absent good reason not to).

Here, however, things can get tricky. Depending on what state you are working in or which federal agency you are dealing with, the ability to acquire files that illuminate the presence or absence of potential vapor concerns can stretch the gamut from 'easy' to 'impossible.' Without the appropriate data, consultants are left to speculate on everything from the type of contamination to its extent and its potential impact to a target property.

Furthermore, given the apparent lack of experience in dealing with vapor concerns amongst the consulting industry, there is no guarantee that a particular consultant knows which questions to ask of the data they may have been able to get their hands on. For instance, at what depth does the contamination occur? Is the contamination present in the unsaturated zone? Do the contaminants readily respond to aerobic bio-degradation? What is the soil composition of the area and what role could that play in vapor migration? How old is the contamination? These are all important questions that can mean the difference between a deal going forward, or the inclusion in the ESA of the three words no client wishes to see: 'Further Investigation Required.'

The one addition to the new VI Guideline that environmental professionals have found of valuable use is the EPA's Vapor Intrusion Screening Level ("VISL") calculator. Rather than using standard tables for the various constituents as in past guidelines, the new VI Guideline implements the VISL calculator which provides a flexible means of determining potential vapor intrusion concentrations based on known subsurface conditions. The calculator user is able to select various fields, including property type, target risk values, hazard quotient, and average groundwater temperature, to establish whether a concentration has exceeded target levels.

Despite its ease of use, the VISL is not without its detractors who point out that its results are often over-conservative. Additionally, constant updating and tweaking by EPA has led to the addition of over 100 chemicals to the list of those classified as volatile. Without a working knowledge of what factors EPA uses to determine volatility or the risk inherent for a given chemical, consultants blindly plugging numbers into the calculator may be overstating the risks of vapor, which can add further delay and cost to deals.

The 'No Further Action' Status Is No Longer the 'Goose That Laid The Golden Egg'

For the longest time, consultants could point to a No Further Action (NFA) letter (or its equivalent) from a state regulator as evidence that no further assessment was necessary for a target property. However, most historic investigations simply did not consider the potential risks associated with vapor. As a consequence, the lack of concern from a state agency regarding contamination left in place does not carry the same weight it once did and must be analyzed by consultants as though it were an active matter.

For instance, a Phase I ESA was being completed for a potential property acquisition identified to be adjacent to an historic dry cleaner site. Regulatory records suggested that a prior 2002 investigation of the dry cleaner revealed groundwater impacted by the dry cleaning solvent perchloroethene (PCE). The release was neither delineated nor was the source area further investigated. Since the PCE release was above the EPA maximum contaminant level, the release was submitted to the state to decide if additional actions were required. The state determined that since water wells and/or other receptors were not identified within a mile-area of the release, no additional remedial actions were required.

Given the scenario, the consultant considered the release to be a CREC. However, since there was a potential presence of vapor migration into the onsite commercial building, and the concentrations identified in the closest groundwater monitoring well "failed" the VISL calculation for a VI carcinogenic risk,

additional sampling was recommended by the consultant to verify that the prior release would not potentially impact soil vapor and, potentially, indoor air quality.

In the above scenario, the potential purchaser of the subject property was left wondering why the environmental consultant was so concerned about a neighboring release, which neither was a responsibility of the subject property owner nor a concern to the state. Additionally, the lack of state vapor migration regulations did not help justify the consultant's opinion that additional investigation should be conducted, making the environmental consultant appear to be a "deal killer" for an issue that even the state does not appear to want to address. Needless to say, clearer communication to a potential purchaser, lender or other client is necessary to help identify the risks that they are willing to assume or dismiss.

Historic State Involvement Only Increases Confusion

As we continue down the road and begin to further identify risks associated with vapor migration, additional concerns may also be realized when property owners and responsible parties begin to inquire about state funded cleanup sites and how vapor migration will be handled.

During a recent property transfer, a petroleum release had been closed in 2004 applying risk-based corrective action (RBCA) concentrations and using state funding. Shallow groundwater was identified at a depth of two-feet below grade surface and benzene concentrations were allowed to remain in groundwater at very high levels.

A new developer was interested in redeveloping the site into a restaurant. The Phase I ESA identified that additional costs would be incurred in dewatering the site, but also that vapor issues may be present given the existing benzene concentrations. The ESA recommended that additional testing be completed to verify the potential exposure, or that a line item be created in the construction budget to mitigate the dewatering and potential vapor issue during development.

Even though regulatory closure had been recently obtained, and the state funding appeared to provide additional security that the new property owner would not be held responsible, the existing conditions posed a potential significant cost for the redevelopment. Although funding had originally been provided for the remedial actions for soil and groundwater at the site, and at-the-time favorable RBCA standards were used, additional expenses were going to be realized by the developer in a state where vapor concerns were not only not regulated, but the state funding for corrective actions did not include future concerns associated with vapor issues. The additional costs to be incurred, coupled with lack of assurance by the regulatory agency that the future property owner would not be responsible for potential issues associated with vapor intrusion, ultimately lead to a failure to acquire and redevelopment the property.

Conclusion

Two years on from publication of the 2013 Standard, the resultant confusion and hand-wringing on the part of consultants as well as developers, commercial property owners, lenders, attorneys, and others in the regulated community has arguably led to deal delays and increased diligence costs.

As we continue to implement the 2013 Standard and utilize the newly published EPA Guidelines, consultants will become more familiar and imaginative with both the real and perceived risks posed by vapor in the transactional due diligence context. In addition, clients and others in the regulated community will need to acquire a working knowledge of the factors that govern the identification of vapor risks, and how those risks can be mitigated at the initial stage of diligence.

It will also be interesting to discover how creative the agencies will become, not only handling the investigation and remediation activities for off-site vapor migration from source areas, but how to fund those cleanups to more stringent standards while not hampering market transactions that otherwise represent a boon to local and regional economies.

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(Endnotes)

1 ASTM E1527-13, Standard Practice for Environmental Site Assessments: Phase I Environmental Site Assessment Process, ASTM International, West Conshohocken, PA, 2013, www.astm.org.

2 *See* ASTM E1527-13 Section 3.2.56 (definition of 'migrate/migration').

3 *See* Addy Brooks & Chris Gilmer, 'Changing Phase I ESA Standards: Are You Ready?', Georgia Environmental Law Section Newsletter (Fall 2013).

4 U.S. EPA, Office of Underground Storage Tanks, 'Technical Guide for Addressing Petroleum Vapor Intrusion at Leaking Underground Storage Tank Sites' (June 2015).

5 U.S. EPA, Office of Solid Waste and Emergency Response, 'OSWER Technical Guidance for Assessing and Mitigating the Vapor Intrusion Pathway from Subsurface Vapor Sources to Indoor Air' (June 2015).

A New Market for Solar Energy in Georgia

By Stephen E. O'Day, Smith, Gambrell & Russell, LLP*

By unanimous votes in both the House and the Senate, the Georgia General Assembly enacted HB 57, the Solar Power Free-Market Financing Act of 2015, sponsored by Rep. Mike Dudgeon (R-Johns Creek).[1] In so doing, the General Assembly created a market for the financing of solar energy that did not previously exist in Georgia or any other Southeastern state.[2] The law has the potential for establishing Georgia as a clear leader in the Southeast in the development of distributed generation ("DG") solar energy projects. To understand how large a step was taken in the legislation, one must evaluate the state of the law prior to the passage of HB 57, and the chilling effect that situation had on development of DG solar projects in Georgia.

The Territorial Act of 1973

In the early 1970s, many parts of rural Georgia still did not have electricity. In order to encourage efficiency in extending electricity to unserved areas, and to avoid duplication of capital investment in transmission and distribution lines, the General Assembly enacted the Territorial Electric Service Act in 1973 ("Territorial Act").[3] Under that law, the Georgia Public Service Commission ("PSC") was directed to establish territories in which electric service providers ("ESP") were given the exclusive rights to the sale of retail electric service to the public.[4] The purposes of doing so were clearly set forth in the Territorial Act: "(1) to assure the most efficient, economical, and orderly rendering of retail electric service within the state, (2) to inhibit duplication of the lines of electric suppliers, (3) to foster the extension and location of electric supplier lines in the manner most compatible with the preservation and enhancement of the state's physical environment, and (4) to protect and conserve lines lawfully constructed by electric suppliers."[5]

The law contained certain exceptions in which limited competition for the sale of electric service was allowed. Thus, when an industrial or other large user of electricity first purchases electricity, any ESP can compete to sign the user up for electric service.[6] Once signed up, however, the customer is permanently required to obtain its electric service from that ESP.

Outside of those limited exceptions, following the effective date of the Territorial Act, the PSC set about assigning exclusive territories to the myriad ESPs in Georgia.[7] Provisions were also included for acquisition of new territories, and how to deal with situations where ESPs had overlapping distribution lines.

1. Definitions in the Territorial Act

Because the Territorial Act establishes a monopolized exception to what most would consider a free market economy, it is important to evaluate the meanings of the terminology used to set apart the market in which Georgia's ESPs were granted government-sponsored monopolies. Not all of the crucial terms, however, were defined in the statute or regulations.

The Territorial Act directed the PSC to designate "assigned areas" to "electric suppliers" "inside which the assignee electric supplier shall have the exclusive right to extend and continue furnishing service."[8] An "electric supplier" is "any electric light and power company subject to regulation by the [PSC], any electric membership corporation furnishing retail service in this state, and any municipality which furnishes such service within this state."[9] "Service" means "retail electric service."[10] Because the term "retail service" or "retail electric service" is the commodity over which ESPs were given a monopoly within their assigned areas, it would seem important to define what retail electric service is. The Territorial Act, however, failed to include a definition of that crucial term.

2. Case law defining the monopolized market

In 1971, the Georgia Supreme Court addressed the question of whether Atlanta Gas Light Company was acting as a public electric utility in contracting to furnish "total energy service," including electricity, to two 25-story buildings and a 70-story building in Peachtree Center in Atlanta. The Court noted that more than 16,000 people would be furnished the electric service in the three buildings. Finding that such a number of people constituted a "significant segment of the public," the Court found that the total energy service was subject to regulation by the PSC as furnishing electric service to the public.[11]

Neither that case nor any other published opinion in Georgia has addressed whether furnishing electric service to a single customer from solar panels located on the property of that customer constitutes "retail electric service" within the meaning of the Territorial Act. Published Opinions of the Attorney General of Georgia, though not binding on courts, do seem to indicate that such an arrangement would not be furnishing retail electric service, and therefore not prohibited under the Territorial Act. A 1969 opinion evaluated factors such as the extent of service, whether the seller holds itself out as ready to serve the public generally, and whether, in other ways, the seller has conducted itself as a public utility. The opinion concluded that the owner of a trailer park who sold electricity to his tenants was not involved in service to the public so as to subject him to the

jurisdiction of the PSC.[12] A 1972 opinion cited the factors described in the 1969 opinion, plus the "significant segment of the public" language from *Atlanta Gas Light*, and opined that furnishing electricity and steam to three companies involved in general manufacturing was not retail electric service subject to the jurisdiction of the PSC.[13]

Although few cases have been decided in Georgia addressing the meaning of the "retail electric service" as used in the Territorial Act, other States that enacted laws with similar purposes and language have addressed the critical issue of the breadth of the electricity market that was reserved exclusively to ESPs. The most recent and comprehensive opinion on the subject was decided by the Iowa Supreme Court in 2014 (referred to herein as "*Eagle Point*").[14] The Iowa Code defined a public electric utility as a company furnishing electricity to the public for compensation.[15] The Iowa Supreme Court in *Eagle Point* evaluated eight factors to determine whether a contract to sell electricity from solar panels to an onsite customer was service to the public so as to require regulation of the solar company as a public utility, and found that it was not.

3. Georgia's electric monopolies before HB 57

From the above rendition, one can easily discern that the scope of the electricity market reserved exclusively to ESPs was, to use Southern terminology, "clear as mud." Neither the General Assembly nor the courts had clearly defined the crucial terms that described the scope of the market carved out for the ESPs.

In this writer's opinion, the reason for the lack of clarity resulted from the technology of the generation of electricity and delivery to the homes and businesses of the State. The market model assumed centralized generation of electricity--usually in large coal-fired steam turbines, nuclear facilities such as Georgia Power's Plant Vogtle, and smaller but still important hydroelectric facilities such as Buford Dam. That centrally-generated electricity was then transmitted over transmission lines, and then distributed over distribution lines to individual homes, businesses, churches, schools, factories and other users of the electricity.

The market model did not contemplate that it would be technologically or economically practicable to generate the electricity on the site at which it would be used--at the home, church, school or restaurant that consumed the electricity--DG of electricity. While there has always been some DG of electricity--think a diesel generator used during a power outage--large scale development and implementation of DG electricity did not occur. The statutory language thus did not contemplate a market for large scale third party development and ownership of DG of electricity for sale to and use by the onsite homes, businesses or institutions.

It was thus inevitable that when technology and other factors drove down the cost of electricity generated onsite by solar panels installed on roofs, parking lots and in ground-mounted systems, a clash would occur between the ESPs whose businesses were built on the government-sponsored monopoly in electricity, and their customers who sought to benefit from onsite generation and sale of clean solar energy in their homes, businesses and institutions. The ESPs took the position that no electrons could be sold by one party to another, even if those electrons were sold to only one person or entity and never entered the transmission or distribution grids operated by the ESPs.

Many customers, however, understandably felt that in an economy built on free market principles, where that market provided choices for how they could purchase and use electric power on their own properties, they should be able to make those choices themselves. In Georgia and elsewhere, customers began signing up for solar systems paid for and owned by third parties, in which the owner of the solar system recouped its investment and made its profit from the sale of electricity to the customer under a so-called Power Purchase Agreement ("PPA")--generally a long term contract for the sale and purchase of electric power from the solar panels installed and owned by the third party. ESPs in Georgia, given their understanding of their exclusive right to sell electricity within their territories, generally contested such PPAs by sending cease and desist letters insisting that only the ESP could sell electricity within its assigned territory. The result was a freezing chill on the development of DG solar energy in Georgia and elsewhere in the Southeast.

Into this breach stepped Rep. Dudgeon and his Solar Power Free-Market Financing Act, which will be referred to for the balance of this article as HB 57.

4. HB 57

Purpose

The General Assembly's purposes in enacting HB 57 were:

- To facilitate investment in solar energy in Georgia
- To provide more opportunity for financing of solar energy in Georgia through utilization of financing options provided by the free market
- To allow reduction or elimination of upfront costs to the property owner in development of solar energy systems
- To allow businesses to offer financing of solar systems in which repayment of the cost is based on the electricity produced by the system, without their being regulated as electric utilities.[16]

Solar Energy Procurement Agreements

HB 57 establishes that the financing of a solar system under an agreement in which the cost is repaid based on the electrical output of the system is legal in Georgia, is not

regulated by the PSC, and cannot be interfered with by the ESPs in Georgia: "Solar technology at or below the capacity limit may be financed by a retail electric customer through a solar financing agent utilizing a solar energy procurement agreement ... ."[17]

"Solar technology" is defined as a system that:

- Generates electric energy that is fueled solely by ambient sunlight (i.e., solar panels)
- Is installed upon property owned or occupied by a retail electric customer
- Is connected to the electric service provider's distribution system on either side of the electric service provider's meter.[18]

"Capacity limit" is defined as "a peak generating capacity in alternating current that is no greater than (A) ten kilowatts, for a residential application; or (B) one hundred twenty-five percent of the actual or expected maximum annual peak demand of the premises the solar technology serves, for a commercial application."[19]

A "retail electric customer" is "a person who purchases electric service from an electric service provider for such person's use and not for the purpose of resale."[20]

A "solar financing agent" is any person "whose business includes the leasing, financing, or installation of solar technology."[21]

Finally, and crucially, a "solar energy procurement agreement" (SEPA) is "any agreement, lease or other arrangement under which a solar financing agent finances the installation, operation, or both of solar technology in which the payments are based on the performance and output of the solar technology installed on the property."[22]

Putting the statutory provisions and definitions together, a market has now been created in Georgia for "free-market" financing of DG solar systems in which third party investors and businesses can own and profit from solar energy systems built across the State, generating power that is used and paid for by the customer who owns or occupies the property served by the solar system. Company A can pay for, build and own the solar system on Customer's property, and Customer's payment can be based entirely on paying for the electricity generated by the solar system.

Limitations and Conditions

1. **Capacity limit.** Because the ESPs were concerned that the legislation could encourage the construction of excess capacity--leading to pressure for sale of that excess power "to the public"--a capacity limit for solar systems financed by SEPAs was included in the law. The limit of 10 kilowatts for residential systems was understood to be sufficient for the vast majority of residences, and was also based upon the standard safety breakers installed by electric utilities for residential service. For all other customers, the capacity limit allows for sizing the solar system at a capacity larger than the peak annual demand of the premises, and allows for expansion and new facilities by including "expected" peak demand in the definition.
2. **Compliance with applicable law.** The solar system must comply with building and electrical codes, and any other applicable laws and ordinances.[23]
3. **Notice.** The customer must give notice to the ESP at least 30 days prior to operating the solar system.[24] This is not a permit requirement--it simply requires the customer to notify the ESP; the customer does not have to await ESP approval.
4. **Multiple premises on a property.** A property that has multiple premises--e.g., a multi-tenant mall, or a school or university with multiple buildings--can have multiple solar systems to serve the separate facilities with electrical demands. In an important limitation, the law does not allow a single "solar technology" to be connected to multiple premises. Also, the cumulative capacity of the multiple solar systems cannot exceed the capacity limit for the premises they serve.[25] These restrictions will require careful technical and legal planning of solar systems financed by SEPAs that are intended to serve properties that have multiple metered facilities.
5. **Non-interference.** Solar systems financed under SEPAs in compliance with HB 57 "shall not be considered the provision of electric service to the public, retail electric service, or retail supply of electricity by the solar financing agent, and neither the retail electric customer nor the solar financing agent shall be considered an electric supplier within the meaning of" the Territorial Act.[26] Thus, such systems are not precluded by the retail electricity monopolies granted to ESPs within their territories in Georgia. Thus, "no electric service provider shall prevent or otherwise interfere with the installation, operation, or financing of solar technology by a retail electric customer through a solar financing agent pursuant to [HB 57]."[27]
6. **Interconnection.** ESPs are allowed to require the electric customer having a solar system financed under a SEPA to comply with certain safety, power quality and interconnection requirements set forth in O.C.G.A. § 46-3-64. For systems with a capacity no more than 10 kilowatts for a residential application and 100 kilowatts for a commercial application, the safety and interconnection requirements are those already provided under the Cogeneration and

Distributed Generation Act of 2001.[28] For larger systems, additional requirements may be imposed, at the cost of the customer or financing agent, but "only those necessary to protect public safety, power quality, and system reliability."[29] That is a new limitation, and is designed to ensure that ESPs do not impose unnecessary requirements that could chill or destroy the new market created by HB 57.

Conclusion.

The conditions and limitations that are contained in HB 57 apply only to solar systems financed under SEPAs. Any person or business can pay cash for, or otherwise finance, solar systems not in compliance with the provisions of HB 57. Thus, HB 57 is at its heart a financing measure--it clearly allows in Georgia the form of financing for DG solar systems that is most popular elsewhere in the country--so-called PPA financing.[30] Now known in Georgia as SEPA financing, it is expected that the new market in financing solar systems created by HB 57 will enable increased development of solar systems on homes, schools, churches, businesses, retail stores and other properties across the State of Georgia, because SEPA financing generally will reduce or eliminate upfront costs, and will allow customer control of electric rates by providing for payment for the electricity produced by the solar system at rates fixed in the long term SEPA. Some solar companies have already begun residential solar programs offering SEPA financing, while those companies and others are increasing efforts to offer solar energy systems to commercial customers like big box retailers and commercial and industrial property managers.[31] As a result, expect to see solar systems blooming across the State during the next year.

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(Endnotes)

1 Solar Power Free-Market Financing Act of 2015, *available at* http://www.legis.ga.gov/Legislation/en-US/display/20152016/HB/57.

2 NC Clean Energy Technology Center, "3rd party solar PV power purchase agreement (PPA)." Database of State Incentives for Renewables and Efficiency, March 2015, *available at* http://ncsolarcen-prod.s3.amazonaws.com/wp-content/uploads/2015/01/3rd-Party-PPA_0302015.pdf. The Database of State Incentives for Renewables and Efficiency is the most comprehensive source of information on state and local governmental policies affecting solar energy and other renewable energy sources. It is operated by the North Carolina Clean Energy Technology Center at North Carolina State University and is funded by the U.S. Department of Energy.

3 O.C.G.A. § 46-3-1, *et seq*.

4 O.C.G.A. §§ 46-3-2, 46-3-4, 46-3-5, 46-3-6, and 46-3-7.

5 O.C.G.A. § 46-3-2.

6 "[O]ne or more new premises (but if more than one, such premises must be located on the same tract or on contiguous tracts of land), if utilized by one consumer and having single-metered service and a connected load which, at the time of initial full operation of the premises, is 900 kilowatts or greater (excluding redundant equipment)." O.C.G.A. § 46-3-8(a).

7 There are a total of 97 electric utilities in Georgia: Georgia Power Company, Savannah Electric and Power Company, the Tennessee Valley Authority, plus 41 electric membership corporations ("EMCs"), https://georgiaemc.com/georgia-emc, plus 53 electric systems run by Georgia municipalities, http://www.psc.state.ga.us/electric/electric.asp.

8 O.C.G.A. § 46-3-3(1).

9 O.C.G.A. § 46-3-3(3).

10 O.C.G.A. § 46-3-3(9).

11 *Atlanta Gas Light v. Pub. Serv. Comm'n*., 228 Ga. 347, 351-352 (1971).

12 1969 Ga. Attorney Gen. Op. 69-27.

13 1972 Ga. Attorney Gen. Op. 72-84.

14 *SZ Enter., LLC d/b/a Eagle Point Solar v. Iowa Util. Bd.*, 850 N.W.2d 441 (Iowa 2014), as corrected (Aug. 14, 2014)

15 Iowa Code § 476.1.

16 O.C.G.A. § 46-3-61.

17 O.C.G.A. § 46-3-63(a).

18 O.C.G.A. § 46-3-62(14).

19 O.C.G.A. § 46-3-62(2).

20 O.C.G.A. § 46-3-62 (11).

21 O.C.G.A. § 46-3-62(13).

22 O.C.G.A. § 46-3-62(12).

23 O.C.G.A. § 46-3-63(a)(1).

24 O.C.G.A. § 46-3-63(a)(2).

25 O.C.G.A. § 46-3-63(e).

26 O.C.G.A. § 46-3-65(a).

27 O.C.G.A. § 46-3-63(b).

28 O.C.G.A. § 46-3-50, *et. seq*.

29 O.C.G.A. § 46-3-64(b).

30 *See* Solar Energy Industries Association, "Third-Party Solar Financing," *available at* http://www.seia.org/policy/finance-tax/third-party-financing.

31 *See, e.g.,* Market Watch, "Hannah Solar Launches Hannah Home Energy in Partnership with Sonnenbatterie Inc.," October 7, 2015, *available at* http://www.marketwatch.com/story/hannah-solar-launches-hannah-home-energy-in-partnership-with-sonnenbatterie-inc-2015-10-07.

U.S. EPA Proposes Sector-Specific Rules for Hazardous Waste Pharmaceuticals

By Karlie Clemons Webb, Troutman Sanders

Under existing regulations, retail pharmacies, hospitals, and other healthcare facilities such as nursing homes are subject to the same U.S. Environmental Protection Agency (EPA) hazardous waste regulations as industrial facilities. Healthcare facilities have for years wrestled with challenges inherent in managing their hazardous waste streams, such as prescription and over-the-counter drugs, pursuant to applicable regulations, while also implementing a management program that is workable in a retail or healthcare setting. Pharmaceuticals, like vitamins or cough medicine, can be deemed waste if expired or unsalable, and can be deemed hazardous if toxic or flammable, for example. National retail pharmacies in particular have struggled with the myriad of deviations in state requirements, as some states have adopted regulations or guidance specific to hazardous waste pharmaceuticals, and others have not.

EPA has recognized the challenges faced by the healthcare sector in complying with Resource Conservation and Recovery Act (RCRA)[1] hazardous waste regulations. On September 25, 2015, EPA published in the Federal Register the proposed *Management Standards for Hazardous Waste Pharmaceuticals*,[2] which proposes healthcare sector-specific requirements for managing hazardous waste pharmaceuticals. While not a comprehensive analysis of the proposed rule, this article highlights several key points in the proposed rule and comments on potential impacts to healthcare facilities.

Rulemaking History

The proposed rule is not EPA's first time recognizing the challenges faced by healthcare facilities with respect to hazardous waste pharmaceuticals. In 2008, EPA proposed to add hazardous waste pharmaceuticals to the Universal Waste Rule as a means of streamlining the management process.[3] After many negative public comments, EPA formally rescinded the proposed rule in 2012. Since that time, the regulated community has provided significant feedback to EPA on issues related to managing hazardous waste pharmaceuticals, which aided EPA in drafting the proposed rule.

Specific to issues faced by retail pharmacies (and other retailers), on February 14, 2014, EPA published its Notice of Data Availability and Request for Comment (NODA),[4] which asked retailers to comment on various issues related to hazardous waste management. Retailers responded on various issues, including, for example, over-the-counter drugs. While EPA has not proposed a rule specific to the retail sector, the NODA confirmed that EPA was listening to retailers' concerns, including concerns related to over-the-counter drugs. It is unclear whether EPA will propose retail-specific hazardous waste regulations applicable to the broader universe of retail consumer products.

Applicability of Proposed Rule

Subpart P. The proposed rule would create a new subpart P under 40 C.F.R. Part 266, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities."[5] Except for Conditionally Exempt Small Quantity Generator (CESQG) healthcare facilities, *hazardous waste* pharmaceuticals generated by *healthcare facilities* would be solely managed under the new 40 C.F.R. Part 266 Subpart P, in lieu of 40 C.F.R. Part 262.[6] A healthcare facility is also given the option of electing to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under Subpart P.[7] "Healthcare facility" is defined broadly in the proposed rule, to include, for example, hospitals, health clinics, pharmacies, and long-term care facilities.[8] "Pharmaceutical" is also defined broadly and would capture over-the-counter medications, including some nicotine-containing products, such as nicotine replacement therapy (NRT) products (gum, lozenges, and patches).[9]

Generator Status. Under the proposed Subpart P, a healthcare facility's hazardous waste pharmaceuticals would not count toward its generator status.[10] This would provide some relief to healthcare facilities, particularly retailers, which, under the current regulatory scheme, often do not maintain a consistent generator status, generally due to fluctuations in the amount of acute hazardous waste generated from month to month, resulting from expired or returned NRT products. Further, because hazardous waste pharmaceuticals, particularly NRT, would no longer count toward a healthcare facility's generator status under the proposed rule, the healthcare facility would likely experience a change in its generator status for its non-pharmaceutical hazardous waste as well.

CESQGs. Under the proposed rule, CESQGs would maintain the conditional exemption under 40 C.F.R. § 261.5.[11] Alternatively, a CESQG could choose to manage its hazardous waste pharmaceuticals pursuant to the proposed Subpart P.[12] EPA also proposes to revise the list of facilities[13] to which CESQGs may ship, to allow CESQGs to send hazardous waste pharmaceuticals to pharmaceutical reverse distributors. [14] Importantly, in determining whether a healthcare facility must manage its hazardous waste pharmaceuticals under the proposed

Subpart P or would remain a CESQG pursuant to 40 C.F.R. § 261.5, the healthcare facility would be required to count all hazardous waste it generates in a calendar month, including both pharmaceuticals and non-pharmaceuticals. Currently a retail pharmacy does not count hazardous waste pharmaceuticals sent to a reverse distributor toward the retailer's generator status. Under the proposed rule, hazardous waste pharmaceuticals sent for reverse distribution pursuant to the proposed rule would be counted toward the retailer's generator status when initially determining whether the retailer is a CESQG or subject to Subpart P.[15] Accordingly, although a particular retailer may currently be a CESQG without counting hazardous waste pharmaceuticals sent for reverse distribution, under the proposed approach, the retailer may no longer be a CESQG.[16]

DEA Regulated Hazardous Waste Pharmaceuticals.

EPA also proposes a conditional exemption for those hazardous waste pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances. Currently, hazardous waste pharmaceuticals that are also DEA controlled substances are subject to both RCRA hazardous waste requirements and the Controlled Substances Act and DEA regulations. The proposal would exempt these hazardous waste pharmaceuticals from the RCRA regulatory requirements, provided the hazardous waste pharmaceuticals are managed in accordance with DEA regulations and ultimately incinerated at a permitted or interim status hazardous waste incinerator or a permitted municipal solid waste incinerator.[17]

Sewer Ban

EPA states that a primary goal in issuing the proposed rule is to restrict the currently acceptable practice of discharging hazardous waste pharmaceuticals to the sewer. The proposed rule would prohibit all healthcare facilities and pharmaceutical reverse distributors from discharging hazardous waste pharmaceuticals to a sewer that passes to a publicly owned treatment works.[18] Importantly, the proposed prohibition would apply to all healthcare facilities.[19] While CESQGs would be exempt from other portions of the proposed rule, as proposed, the sewer prohibition would equally apply to CESQGs.[20] EPA anticipates that the proposed prohibition would reduce the volume of hazardous waste pharmaceuticals discharged annually by approximately 6,400 tons, and save approximately $4.3 million annually in the cost of eliminated wastewater treatment.[21] The proposed rule would not restrict sewering of non-hazardous waste pharmaceuticals.

Reverse Distribution of Pharmaceuticals

Retail pharmacies rely heavily on the reverse distribution process to obtain monetary credit for expired, damaged, recalled, or discontinued pharmaceuticals. In short, a retailer sends pharmaceuticals to the reverse distributor, and the reverse distributor then determines whether a given pharmaceutical is eligible for manufacturer credit. While reverse distribution of pharmaceuticals is not currently addressed by statute or regulation, EPA has addressed reverse distribution through guidance and in the preamble to the 2008 Universal Pharmaceutical Waste rule.[22] Historically EPA's position has been that a pharmaceutical returned for credit through reverse distribution does not become a waste until a determination is made to discard the pharmaceutical.[23] Accordingly, EPA considered pharmaceuticals not to be a waste at the retail pharmacy because the credit determination has not yet been made. Several states have also addressed reverse distribution through guidance materials, most of which accepted EPA's position. A couple states, however, rejected EPA's position and instead concluded pharmaceuticals are a waste at the retail pharmacy, prior to being sent to the reverse distributor.[24] This inconsistency between states has presented challenges for national retail pharmacies that have established a consistent, national approach to reverse distribution of pharmaceuticals.

In the preamble to the proposed rule, EPA explicitly changes its position as to when a pharmaceutical becomes a waste:

> *EPA is proposing to reinterpret its position such that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility.*[25]

However, EPA then clarifies that although a waste at the healthcare facility, the proposal would allow "potentially creditable hazardous waste pharmaceuticals"[26] to be sent to a "pharmaceutical reverse distributor,"[27] which would then facilitate credit. Under the proposed rule, "potentially creditable hazardous waste pharmaceutical" would mean a hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is unused or un-administered and either unexpired or less than one year past expiration date. Non-creditable hazardous waste pharmaceuticals"[28] would not be eligible for reverse distribution. While potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals would both be managed under the proposed Subpart P, different management requirements would apply.

EPA's proposed requirements specific to reverse distribution of pharmaceuticals is likely to be a retail pharmacy's biggest concern with the proposed rule. The proposed rule raises questions on whether all pharmaceuticals sent for reverse distribution will be considered a waste. Importantly, although the preamble does not clearly make this point, EPA clarified the following in an Oct. 13, 2015, webinar: "If a pharmaceutical product is redistributed for reuse or legitimately recycled, then it is not considered a solid waste or hazardous waste and is not covered by this proposed rule." However, a challenge inherent in sending

pharmaceuticals for reverse distribution is that a retail pharmacy is not likely to know the ultimate disposition of the pharmaceuticals. Accordingly, it may be difficult or impracticable for retailers to document how thousands upon thousands of pharmaceuticals sent for reverse distribution are ultimately reused or legitimately recycled.

Potentially Creditable Hazardous Waste Pharmaceuticals.

EPA did not propose onsite management standards for potentially creditable hazardous waste pharmaceuticals while at a healthcare facility, such as labeling and accumulation time limits.[29] EPA notes in the preamble that fewer management requirements are warranted for potentially creditable hazardous waste pharmaceuticals, as EPA believes potentially creditable hazardous waste has a lower risk of release.[30]

The proposed rule would require that the healthcare facility shipping potentially creditable pharmaceuticals to a pharmaceutical reverse distributor follow specific tracking requirements, including, for example, notifying the pharmaceutical reverse distributor of an upcoming shipment prior to shipping the pharmaceuticals and notifying the shipper and pharmaceutical reverse distributor of a discrepancy if the healthcare facility does not receive confirmation of delivery within seven calendar days of shipment.[31]

Non-Creditable Hazardous Waste Pharmaceuticals.

Where a healthcare facility knows a hazardous waste pharmaceutical would not be creditable, the healthcare facility would be required to manage the pharmaceutical as a non-creditable hazardous waste pharmaceutical, which the proposed rule would not allow to be sent to a pharmaceutical reverse distributor.

Non-creditable hazardous waste pharmaceuticals would be subject to more stringent management standards than those proposed for potentially creditable hazardous waste pharmaceuticals. For example, unlike potentially creditable hazardous waste pharmaceuticals, non-creditable hazardous waste pharmaceuticals must be labeled "Hazardous Waste Pharmaceuticals;"[32] may be accumulated onsite for no more than one year, unless an extension is otherwise granted;[33] must be shipped on a hazardous waste manifest,[34] except waste codes are not required on the manifest; and each shipment must be either shipped to an interim status or permitted treatment, storage, and disposal facility via a licensed hazardous waste transporter.[35] Importantly, although non-creditable hazardous waste pharmaceuticals would be subject to more stringent management standards, like potentially creditable hazardous waste pharmaceuticals, non-creditable hazardous waste pharmaceuticals would also not count toward the healthcare facility's generator status.[36]

Nicotine-Containing Products

Retail pharmacies often register as LQGs based solely on

the amount of acute hazardous waste generated as a result of expired or returned NRT. NRT and other nicotine-containing products, such as e-cigarettes, are classified as P075 listed acute hazardous waste when discarded. Historically there has been little opportunity to return NRT for manufacturer credit through the reverse distribution process. Accordingly, under current regulations, when a healthcare facility accumulates more than 2.2 pounds of expired or returned NRT or other nicotine-containing products, the healthcare facility is subject to LQG regulations.

In recent years, such as in response to the Feb. 14, 2014, NODA, retail pharmacies have urged EPA to reconsider its position on nicotine contained in nicotine-containing products. Although EPA did not propose language related to nicotine-containing products, EPA requested comment on two possible approaches: (1) exempting P075 listing for Food and Drug Administration (FDA)-approved, over-the-counter NRT products; and (2) exempting P075 for low-concentration nicotine-containing products.[37] EPA noted it is working with the FDA to obtain FDA's risk evaluation for NRT products, and EPA requests that the healthcare sector provide other data to support any future regulations EPA may adopt specific to nicotine-containing products.

While it remains to be seen whether and how EPA will address nicotine-containing products, as proposed, NRT is within the definition of "pharmaceutical." Under the proposed Subpart P, the weight of pharmaceuticals would not count toward the healthcare facility's generator status. Because retailers often only reach LQG status as a result of exceeding the acute hazardous waste threshold because of NRT, the proposed rule would reduce the likelihood that most retail pharmacies would become LQGs. Likewise, depending on the weight of non-pharmaceutical hazardous waste, which would count toward the healthcare facility's generator status, retailers currently registered as LQGs would likely become either SQGs or CESQGs.

Importantly, it is currently unclear whether e-cigarettes, which contain nicotine, and e-cigarette refill liquids would be a "pharmaceutical" under the proposed rule. If e-cigarettes were not a "pharmaceutical," they would not be subject to the proposed Subpart P and would thus count toward a facility's generator status, just as all NRT currently does under 40 C.F.R. § 262. EPA requested comment on whether e-cigarettes and e-cigarette refill liquids should be considered a pharmaceutical.[38]

U.S. EPA's Proposed Generator Improvements Rule

On Sept. 25, 2015, the same day EPA's proposed hazardous waste pharmaceuticals rule was published in the Federal Register, EPA's proposed *Hazardous Waste Generator Improvements* rule also was published in the Federal Register.[39] While the proposed pharmaceuticals rule would apply only to healthcare facilities, the proposed generator rule would apply to all hazardous waste generators, ranging from healthcare facilities to industrial facilities. Because of the proposed generator rule's broader scope and the uniqueness of managing hazardous waste pharmaceuticals, the proposed generator rule alone would present challenges beyond the existing compliance challenges faced by the healthcare facilities.

For example, the proposed generator rule would require SQGs and LQGs to maintain waste determination documentation for solid waste determined to be non-hazardous.[40] Currently a hazardous waste generator is required to document waste determinations for solid waste determined to be *hazardous* (but not non-hazardous). As retailers commented to EPA in response to the Feb. 14, 2014, NODA, this requirement is particularly challenging for retail pharmacies because a retailer is likely to have thousands of products in inventory at any given time, and is even more challenging for close-out retailers that do not maintain a consistent inventory. Further, manufacturers rarely provide ingredient-level information needed to make waste determinations. Heightening the documentation requirements to also include solid waste determined to be non-hazardous would further increase the burden on retail pharmacies.

In the proposed generator rule, EPA attempted to provide some flexibility to allow CESQGs[41] and SQGs to occasionally generate higher volumes of hazardous waste without having to change the facility's generator status.[42] As drafted, however, retail pharmacies likely would not qualify. Among other things, to qualify for an episodic event, there must only be one episodic event per year, unless otherwise approved by EPA; the generator must notify EPA at least 30 days prior to initiating a planned episodic event or within 24 hours after an unplanned episodic event, or as soon as possible depending on the circumstances; and the generator must ship the waste to a RCRA-designated disposal facility within 45 calendar days from the start of the episodic event.[43] A retail pharmacy is often unaware it generated LQG quantities until the waste vendor conducts a hazardous waste pickup. Accordingly, the facility would not have notified EPA of an upcoming episodic generation event, and the facility would likely be well past the 24-hour period for notifying of an unplanned event. The retail pharmacy may also be well past the required 45-day pickup timeframe, since a CESQG is not subject to accumulation time limits and an SQG may lawfully accumulate hazardous waste onsite for up to 180 days.[44]

EPA issued the proposed hazardous waste pharmaceuticals rule and proposed generator rule on the same day, and public comments to both rules are due to EPA on December 24, 2015. To the extent EPA also issues *final* rules simultaneously, many requirements in the proposed generator rule -- such as waste determination documentation, heightened labeling requirements, and a requirement to obtain confirmation from emergency responders that they will provide services -- may

not apply to many healthcare facilities, since many healthcare facilities would likely move down in generator category to a CESQG. However, because of the uncertainty surrounding whether and when EPA will issue each final rule, it remains to be seen to what extent certain challenging requirements in the proposed generator rule will affect retail pharmacies.

Conclusion

EPA appears to recognize many of the challenges faced by healthcare facilities in managing hazardous waste pharmaceuticals, and has made an effort to streamline applicable requirements. Healthcare facilities should carefully review EPA's proposed pharmaceuticals rule and consider commenting to EPA on issues concerning to operations. Healthcare facilities should also parse EPA's proposed generator rule, and consider how the proposed rule would affect healthcare facilities. Because we cannot be certain whether EPA will issue the final hazardous waste pharmaceuticals and generator improvements rule simultaneously, healthcare facilities should analyze each proposed rule with the assumption that the other will not be adopted and comment accordingly. Public comments for both proposals are due Dec. 24, 2015.

(Endnotes)

1 42 U.S.C. 6902 et seq. (1976).
2 80 Fed. Reg. 50,014 (Sept. 25, 2015).
3 Proposed Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. 73,520 (Dec. 2, 2008).
4 *Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices To Enhance Effectiveness to the Resource Conservation and Recovery Act Program*, 79 Fed. Reg. 8,926 (Feb. 14, 2014).
5 Proposed Rule 40 C.F.R. § 262.10 (m)-(n).
6 The proposed rule would only apply to *hazardous waste* pharmaceuticals generated by *healthcare facilities*. The proposed rule would not apply to non-healthcare facilities (except pharmaceutical reverse distributors) generating hazardous waste pharmaceuticals. The proposed rule also would not apply to healthcare facilities' non-pharmaceutical hazardous waste and non-hazardous waste pharmaceuticals.
7 80 Fed. Reg. 58,085.
8 "*Healthcare facility* means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals." Proposed Rule 40 C.F.R. § 266.500.
9 "*Pharmaceutical* means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals." Proposed Rule 40 C.F.R. § 266.500.
10 80 Fed. Reg. 58,050.
11 Proposed Rule 40 C.F.R. § 266.501(a).
12 Proposed Rule 40 C.F.R. § 266.501(b).
13 *See* 40 C.F.R. § 261.5.
14 Proposed Rule 40 C.F.R. § 266.504(a).
15 80 Fed. Reg. 58,068.
16 80 Fed. Reg. 58,068.
17 Proposed Rule 40 C.F.R. § 266.506.
18 Proposed Rule 40 C.F.R. § 266.505.
19 Proposed Rule 40 C.F.R. § 266.505.
20 Proposed Rule 40 C.F.R. § 266.505; 80 Fed. Reg. 58,046.
21 80 Fed. Reg. 58,064.
22 Amendment to the Universal Waste Rule: Addition of Pharmaceuticals, 73 Fed. Reg. at 73,525.
23 *See* Sylvia Lowrance to Mark J. Schulz on May 16, 1991 (RCRA Online # 11606); Alan Corson to Steven Wittner on May 13, 1981 (RCRA Online #11012).
24 For example, the New Mexico Environmental Department issued a May 14, 2014, *Fact Sheet For Hazardous Waste Pharmaceuticals*, which states that NMED "does not recognize the reverse distribution of expired hazardous waste pharmaceuticals," and that "[o]nce a product has expired it is considered a waste and must be disposed of in accordance with hazardous waste regulations."
25 Proposed Rule 266.502(i); 80 Fed. Reg. 58,043.
26 The term does not include "evaluated hazardous waste pharmaceuticals," residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals." Proposed Rule 40 C.F.R. § 266.500.
27 EPA proposes stringent standards applicable to pharmaceuticals reverse distributors, similar to current regulations applicable to LQGs, with added inventory and tracking requirements. *See* Proposed Rule 40 C.F.R. § 266.510. This article does not focus on the proposed requirements specific to pharmaceuticals reverse distributors.
28 "*Non-creditable hazardous waste pharmaceutical* means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit." Proposed Rule 40 C.F.R. § 266.500.
29 *See* Proposed Rule 40 C.F.R. § 266.503.
30 80 Fed. Reg. 58,044.
31 Proposed Rule 40 C.F.R. § 266.509(a).
32 Proposed Rule 40 C.F.R. § 266.502(e).
33 Proposed Rule 40 C.F.R. § 266.502(f).
34 Proposed Rule 40 C.F.R. § 266.508.
35 Proposed Rule 40 C.F.R. § 266.508.
36 80 Fed. Reg. 58,040.
37 80 Fed. Reg. 58,072-58,073.
38 80 Fed. Reg. 58,073.
39 80 Fed. Reg. 57,918.
40 Proposed Generator Improvements Rule 40 CFR § 262.11 (e).
41 CESQGs are referred to as "Very Small Quantity Generators" under EPA's proposed generator rule. 80 Fed. Reg. 57,919.
42 Proposed Generator Improvements Rule 40 CFR § 262.232.
43 80 Fed. Reg. 57,973.
44 80 Fed. Reg. 57,923.

New Legislation Could Mark Trend that Would Bring More Timber Production to Georgia's National Forests

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New US Forest Service management projects promise to simultaneously benefit threatened and endangered species and reinvigorate logging and timber sales in Georgia's National Forests. The 2004 Chattahoochee-Oconee National Forests Land and Resource Management Plan calls for 10,000 acres of early-successional habitat (ESH) (important for many wildlife species) across the Chattahoochee Forest's nearly 800,000 acres. New proposals like the Upper Warwoman and Cooper Creek projects would create thousands of acres of ESH. Advocacy from sportsman's groups and influence from policy makers could convince the Forest Service to undertake more ESH projects in Georgia. New legislation recently passed by the US House of Representatives is designed to simplify this process for government agencies, but will also increase the difficulty of public challenges to the land management proposals.

New ESH Projects in Georgia

No exact definition exists for early-successional habitat, but this type of forest habitat shares a few key characteristics. Namely, they are open areas with no canopy cover or only scattered trees.[1] Settings that typify ESH include abandoned farmlands, forests heavily damaged by wind, fire, or ice, and recently harvested forests.[2] ESH requires intense or recurring disturbances, like harvesting, clearcuts, or prescribed burns, to be maintained.[3]

Some scientists and activists worry that the national forests have become too homogenous and are lacking in less mature forest habitat.[4] To counteract that problem, the 2004 Chattahoochee-Oconee National Forests Land and Resource Management Plan calls for the creation and maintenance of 10,000 acres of young and open forest habitat, including woodlands, savannas, and grasslands, that fit the mold of ESH across the Chattahoochee National Forest.[5] The plan calls for an additional 1,000 acres in the Oconee National Forest.[6] The National Wild Turkey Federation has been a strong proponent of these requirements and has worked with the US Forest Service in Georgia to create more young forest habitat specifically to protect the endangered red-cockcaded woodpecker and reduce risks to the forest from wild fires.[7] The Forest Service has now begun work on a number of projects that will create significant new areas of land that could be categorized as ESH, including projects in the Cooper Creek, Upper Warwoman, and Fightingtown Creek Watersheds.

The Upper Warwoman Landscape Management Project will create 70 acres of ESH around 12 existing wildlife openings in Rabun County that average around one acre in size.[8] The Forest Service began soliciting public comment on the plan in 2012, and published its final decision on October 31, 2015. The Cooper Creek Watershed Project as originally scoped would create 253 acres of ESH in Union County, retaining approximately 20 ft^2 of basal area (BA) of overstory trees per acre.[9] Basal area refers to the amount of land occupied by a tree's trunk. The project would also create an additional 764 acres of woodland ESH, retaining less than 60 ft^2 BA per acre.[10] The initial public comment period on this project closed in June, and a draft environmental assessment, along with a second public comment period, is expected in late 2015 or early 2016. The Fightingtown Creek Early Successional Habitat Project has been proposed to address a need to create between 192 to 484 acres of ESH in Fannin County.[11] The initial public comment period closed in September, and a subsequent public comment period and a final decision are expected in 2016.

These projects and others like them have been and will continue to be improved through public participation in the planning process, but new legislation before Congress could threaten the public's ability to influence management decisions.[12]

New Legislation Could Roll Back NEPA Requirements

H.R. 2647, the Resilient Federal Forests Act of 2015, which the US House of Representatives passed in July, would dramatically reshape how the public participates in the project planning process on National Forests.[13] The Passage of this bill could also mark the continuation of a trend that began in 2014 when Congress passed legislation loosening NEPA regulations for some forest management projects.[14] Under the Resilient Federal Forests Act, the Forest Service would only be required to evaluate two options during its NEPA review of a project developed through a collaborative process – the project as proposed and a no-action alternative.[15] "Collaborative process" is defined as, "a process relating to the management of National Forest System lands or public lands by which a project or activity is developed and implemented by the Secretary concerned through collaboration with interested persons, as described in section 603(b)(1)(C) of the Healthy Forests Restoration Act of 2003 (16 U.S.C. 6591b(b)(1)

(C))."[16] The HFRA defines "collaborative process" as a process that "includes multiple interested persons representing diverse interests; and (ii)(I) is transparent and nonexclusive; or (II) meets the requirements for a resource advisory committee."[17]

The 2014 Farm Bill already created a NEPA exemption in the HFRA for any collaborative projects in areas afflicted by disease or insect infestation covering less than 3,000 acres and related to restoration efforts that maximize retention of old growth and large trees and maintain or restore ecological integrity based on the best available scientific information.[18] The Resilient Federal Forests Act increases the acreage limit for categorically excluded projects meant to address disease or insect infestation and other issues, including hazardous fuel reduction, from 3,000 acres to 5,000 acres if not part of a collaborative process and to 15,000 acres if part of a collaborative process.[19] The Act also categorically excludes salvage logging, ESH creation or maintenance, and activities meant to improve, restore, or reduce the risk of wildfire on up to 5,000 acres. [20] The Act places no acreage limits on the two-alternatives provision requiring the relevant agencies to consider only the activity as proposed or no action for projects developed through a collaborative process.[21] In other words, if the Forest Service solicits the input of a few representative individuals in the planning process and its project impacts less than 15,000 acres, it is relieved of its obligation to prepare an environmental assessment or hear and consider general public comments, and no matter the size of the project, the Forest Service would no longer have to consider a wide set of alternatives submitted through public comments. For many of its projects less than 5,000 acres, no collaboration, public input, or EAs are required.

The Resilient Federal Forests Act also creates a special litigation requirement for lawsuits that would challenge projects developed through a collaborative process.[22] Namely, plaintiffs challenging such a project would be required "to post a bond or other security equal to the anticipated costs, expenses, and attorneys fees" of the Forest Service, and all proceedings would be stayed until the bond or security was paid.[23] Any funds remaining after paying the litigation costs of the agency would be returned to the plaintiff.[24] Only if the plaintiff ultimately prevails on the merits on every cause of action brought against the agency would the funds be returned in total to the plaintiff.[25]

Conclusions

Given the recent and pending legislation loosening NEPA regulations for ESH and collaborative projects combined with the apparent trend toward more ESH projects on Georgia's National Forests, the timber industry, environmental activists, and the larger public could find themselves in a very different position in how they interact with the Forest Service. While collaboration requirements will continue to require some sort of diverse public input on forest management projects, interested stakeholders nevertheless could lose some opportunities to participate in the planning process traditionally provided by NEPA. If the trend towards loosening NEPA regulations continues, possibly creating categorical exemptions for all ESH projects, many more opportunities for public involvement could be sacrificed in order to expedite forest management.

If the Resilient Federal Forests Act becomes law, projects like those at Cooper Creek, Fightingtown Creek, and the Upperwoman Creek that seek to create significant new areas of ESH would be categorically excluded from the public engagement process currently provided by NEPA. Projects like those carried out in partnership with the National Wild Turkey Federation would also be exempted from the public process because they seek to create ESH and because they would reduce the fuel load for wildfires. While this streamlined process might allow the Forest Service to move more quickly from project proposal to project implementation, the limited public process could also deprive Georgia's small staff of Forest Rangers of valuable insights from dedicated public partners.

(Endnotes)

1 Cathryn H. Greenberg, et al., *Sustaining Young Forest Communities, in* 21 Managing Forest Ecosystems 1, 4 (Cathryn H. Greenberg et al. eds., 2011), *available at* http://www.nrs.fs.fed.us/pubs/jrnl/2011/nrs_2011_greenberg_001.pdf.

2 Id.

3 Id. at 4-5.

4 Legislation to Address Forest Policy Reform and Encourage Active Forest Management: Hearing on H.R. 2647 Before the Subcomm. on Fed. Lands of the H. Comm. on Natural Resources, 114th Cong. 2 (2015) (statement of Becky Humphries, Chief Conservation Officer, the National Wild Turkey Federation), *available at* http://naturalresources.house.gov/uploadedfiles/humphriestestimony.pdf.

5 U.S. Dep't of Agric. Forest Serv. S. Region, Chattahoochee-Oconee National Forests Land and Resource Management Plan 2-6. (2004) *available at* http://www.fs.usda.gov/land/conf/landmanagement (follow "The Land and Resource Management Plan" hyperlink; then follow "Chapter 2" hyperlink).

6 Id.

7 Humphries statement at 2-3.

8 U.S. Dep't of Agric. Forest Serv. S. Region Chattahoochee Nat'l Forest Chattooga River Ranger Dist., Final Environmental Assessment Upper Warwoman Landscape Management Project 9, 14. (2015), *available at* http://www.fs.usda.gov/project/?project=8722 (follow "Upper Warwoman Final EA" hyperlink under "Decision").

9 U.S. Dep't of Agric. Forest Serv. S. Region Chattahoochee Nat'l Forest Blue Ridge Ranger Dist., Request for Comments: Cooper Creek Watershed Project 6 (2014), *available at* http://www.fs.usda.gov/project/?project=44385 (follow "Coopers Creek Watershed Scoping Ltr" hyperlink under "Scoping").

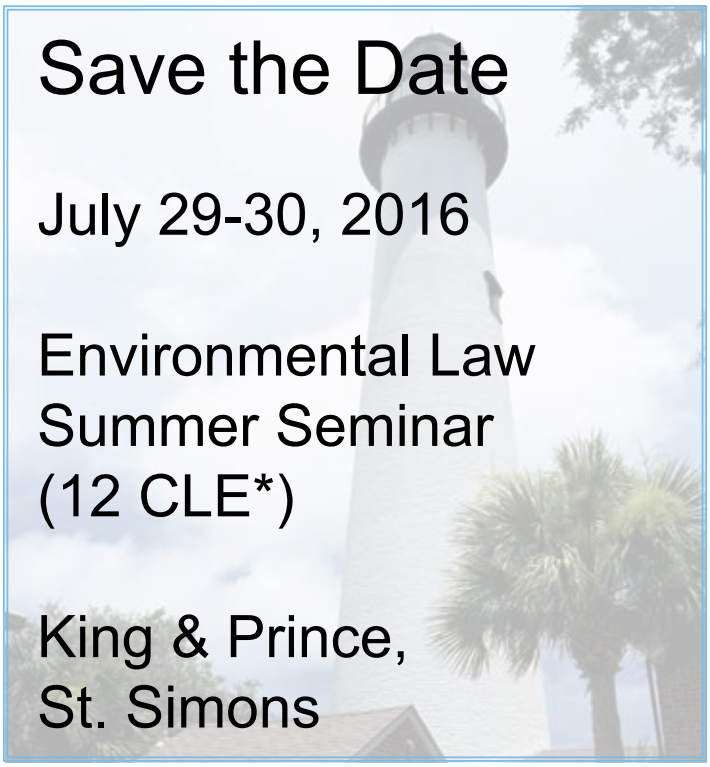
10 Id. at 6-8.

11 U.S. Dep't of Agric. Forest Serv. S. Region Chattahoochee Nat'l Forest Conasauga Ranger Dist., Scoping Notice: Fightingtown Creek Wildlife Habitat Project 4. (2015), *available at* http://www.fs.usda.gov/project/?project=44961 (follow "Fightingtown Scoping Letter" hyperlink under "Scoping").

12 Hearing on Discussion Draft on Forest Resilience: Hearing on H.R. 2647 Before the Subcomm. on Fed. Lands of the H. Comm. on Natural Resources, 114th Cong. 2 (2015) (statement of Eric Biber, Professor, University of California, Berkeley, School of

Law), *available at* http://naturalresources.house.gov/uploadedfiles/bibertestimony.pdf; see U.S. Dep't of Agric. Forest Serv. S. Region Chattahoochee Nat'l Forest Chattooga River Ranger Dist., Upper Warwoman Draft Environmental Assessment Response to Comments Received during the 60 Day Notice and Comment Period 3 (2015) ("Based on public concerns over the proposed 'reroute', the District Ranger has decided to drop the proposed Tuckaluge Road relocation from the project …"), *available at* http://www.fs.usda.gov/project/?project=8722 (follow "Upper Warwoman Appendix K Draft EA Response to Comments" hyperlink under "Analysis").

13 Resilient Federal Forests Act of 2015, H.R. 2647, 114th Cong. (2015).
14 Agricultural Act of 2014, Pub. L. No. 113-79, § 8204, 128 Stat. 649, 916-918 (2014) (codified as amended at 16 U.S.C. § 6591b).
15 Resilient Federal Forests Act at § 101.
16 Id. at § 2(3).
17 16 U.S.C. § 6591b(b)(1)(C) (2015).
18 Id. at § 6591b(c)(1), § 6591b(b)(1)(A)-(B); Agricultural Act of 2014 at § 8204.
19 Resilient Federal Forests Act at § 102.
20 Id. at § 103-104, 106.
21 Id. at § 101.
22 Id. at §§ 301-302.
23 Id. at § 302(a).
24 Id. at § 302(b)(3).
25 Id. at § 302(c).



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