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Abstract

Healthcare units generate substantial amounts of hazardous or potentially hazardous wastes as by-products of their medical services. The inappropriate management of these wastes poses significant risks to people and the environment. Within the countries of the European Union (EU), the management of HCW is strictly regulated by law. Measures pertaining to the collection, storage, treatment and disposal of hazardous waste are construed to ensure that the waste management process takes place in conditions that protect the environment and human health. Despite the growing awareness by legislators that compliance with the applicable regulations is essential to achieve the best environmental protection, little is known about the compliance of the increasingly large numbers of private EU outpatient healthcare facilities with these measures. Using a large survey of over 700 private outpatient healthcare facilities in the EU, this study finds that overall compliance with the law is far from ideal, and identifies important sources of variability in compliance behavior with each of the measures comprising the HCW legislation.

Keywords: Healthcare waste, regulation, management measures, compliance

JEL Classifications: I18, Q53

1. Introduction

Healthcare units generate substantial amounts of hazardous or potentially hazardous wastes as by-products of their medical services. The inappropriate management of these wastes poses significant risks to people and the environment. Environment problems in terms of air, water and land pollution arise from the mere generation of healthcare waste (HCW) and from the process of handling, treatment and disposal. Extensive research conducted in the last decades has established that the appropriate management of these wastes significantly reduces the risks to the environment, as well as the costs associated with its disposal (eg., Fay et al., 1990; Bencko and Culikova, 1993; Pruss et al., 1999; Tudor et al., 2005; Tsakona et al., 2007). Within the countries of the European Union (EU), the management of HCW is strictly regulated by law in order to prevent the negative impacts of hazardous wastes on the environment and human health (Directive 91/689/EEC; Directive 2008/98/CE). Although legal provisions pertaining to the collection, storage, treatment and disposal of hazardous waste date back to the 1990s, little is known about the compliance of the increasingly large numbers of private EU outpatient healthcare facilities (HCF) with each of these legal provisions, or about sources of variability in compliance behavior. This study uses data collected by a large survey of over 700 small private HCFs distributed all over Portugal, a full member of the EU since 1986 where 50% of outpatient care is currently dominated by private operators, in order to assess compliance behavior with each of the existing legal provisions aiming at the safe management of HCW, and identify possible determinants of their compliance behavior.

2. Legislative framework

In line with the EU legislation, the legal provisions concerning the management of HCW in Portuguese law establish that the responsibility for its management belongs to the *producers* of such waste, which is legally defined as "*the waste resulting from medical activities taking place in healthcare facilities, prevention activities, diagnosis, treatment, rehabilitation and research, related to human beings or animals, in pharmacies, in forensic medicine, in teaching, and in any other involving invasive procedures such as acupuncture, piercing and tattoos*" (Dec. Lei 178/2006).

The regulatory framework also establishes that the treatment of HCW must be differentiated according to the type of waste produced. A classification system for HCW is established by law (Despacho 242/96, 13 August), separating HCW in four categories or groups: Group I – this waste is considered to be equivalent to urban waste, presenting no special requirements in its treatment; Group II – this is non-hazardous medical waste, not subject to specific treatments, and may be treated as urban waste; Group III – this is considered as biohazard medical waste, requiring incineration or other effective pre-treatment with a view to subsequent disposal as urban waste; Group IV – this group comprises various types of hazardous waste subject to mandatory incineration. Thus, the first two groups of waste are deemed *non-hazardous* waste, while the last two are deemed *hazardous* waste. This waste classification can be linked to the 18th chapter (on HCW) of the European waste catalogue established by Commission Decision 2000/532/EC, which is a mandatory classification for all EU members.

In addition to this classification system, the same legal text establishes five specific requirements to handle HCW in order to minimize its negative impacts on the environment. These requirements are detailed in Table 1, and include waste segregation at the source, use of appropriate colored containers, availability of different storage

places for hazardous and non-hazardous waste, minimum storage capacity, and the existence of a waste management plan (WMP) at the facility level.

In order to better achieve compliance with these requirements, the regulatory framework also contemplates a number of policy measures to be implemented at the facility level, namely that the HCFs shall provide education and training (E&T) opportunities on waste handling issues to their staff; appoint an individual responsible for the management of the waste within the facility; and, implement regular internal audits.

3. The survey

A survey was designed and sent out to the HCFs based in continental Portugal, and registered at the office of the Portuguese Health Regulatory Entity (HRE). Answers to the survey were collected during March – May 2010 using an electronic survey platform developed by HRE. Rough estimates based on the HRE data indicate a response rate of about 20% from the private outpatient HCFs, a figure that is common in studies assessing compliance with environmental regulations (eg, Botelho et al., 2005, Marinkovic et al., 2008). In line with the figures for high-income countries, the estimated production of HCW by the largest producers (hospitals) in Portugal is about 7.0 Kg/(occupied bed.day), and the private outpatient HCFs account for at least 20% of the HCW produced at the national level (APA, 2010; Almeida (2010)). The facilities in the sample indicate an average annual production of 444 Kg and 39 Kg of Group III and Group IV waste, respectively. This corresponds to an average weekly production of 9.3 Kg of Group III and Group IV waste, a figure that sits well with the production estimate for all small producers in Portugal (LPN, 2010). In addition, the average sample production of Group IV waste corresponds to 8% of the total production of Group III

and Group IV waste as predicted by the Portuguese Environmental Agency (APA, 2010). Thus, the information provided by the sampled facilities conforms to the predictions made by the relevant national entities concerning the population of HCFs.

The survey was composed of two broad parts. One part consisted on questions eliciting the HCFs' compliance with each of the legal requirements detailed in Table 1. It also included questions eliciting their use of the policy variables contemplated in the regulatory framework. In particular, policy variables elicited in the survey were whether the HCF has appointed a person responsible for waste management (*Responsible for WM*); whether internal waste audits have been regularly conducted (*Regular Audits*); and, whether training opportunities on waste handling issues have been provided to the HCF's staff (*Education and Training*). All these variables are expected to impact positively the HCFs' compliance with the legal requirements in Table 1. The other part of the survey consisted on questions concerning the amount of the various types of medical waste generated within the HCF, along with questions regarding a general characterization of the HCFs. Because previous studies have found the size of firms and their region of location to be significant determinants of environmental compliance (eg., Botelho et al., 2005, Rahman et al., 2010, Rousseau, 2009), the latter set of questions included the number of workers in the HCF, their region of location, and the type of services provided (*Type of Healthcare Facility* --each HCF could indicate several types of services). The variables pertaining to the general characterization of the HCF are, therefore, included as control variables in the statistical analysis below.

4. Results

After discarding observations with missing values for the relevant questions asked in the survey, the working sample consists of 741 private outpatient HCFs. A

characterization of their compliance with the legal requirements previously identified is presented in Table 2.

All of these HCFs indicate that the waste produced is segregated at the source as required by law. In addition, about 91% indicate that the waste is stored at a temporary storage place in the colored containers specified in the legislation. However, only 30% of the HCFs comply with the requirement of storing the hazardous waste in a different place from that used to store the non-hazardous waste. Compliance with the requirement that the period between collections is not to exceed 7 days is observed by only 23% of the HCFs. Finally, only 34% of the HCFs indicate having the WMP as required. Thus, apart from segregation, compliance with waste management regulations is in general quite unsatisfactory, and the most problematic requirement appears to be the required periodicity between collections, with more than 75% of the units failing to comply with it.

In order to identify important sources of variability in compliance behavior with each of the specific requirements comprising the HCW legislation, the data is analyzed using the binary response of the HCFs concerning compliance with each of the legal requirements as the dependent variables in multivariate logit models. The logit model allows for estimating the probability that compliance occurs or not by predicting the binary dependent outcome from a set of explanatory variables, and entails a likelihood function that is constructed to be appropriate for binary dependent variables. In this context, let the dependent variable y_i be 1 if HCF i complies with requirement j, and 0 otherwise. The simplest formulation would be to specify the probability of compliance π_i as a linear function of the explanatory variables: $\pi_i=x_i\beta$, for vector of explanatory variables x_i, and parameter vector β. This formulation is known as the linear probability model, and is often estimated from individual data using ordinary least

squares (OLS). One problem with the linear probability model is that the probability π_i on the left-hand-side has to be between zero and one, but the linear predictor $x_i\beta$ on the right-hand-side can take any real value, so there is no guarantee that the predicted values will be bounded between zero and one unless complex restrictions are imposed on the coefficients. A simple solution to this problem is to transform the probability to remove the range restrictions, and model the transformation as a linear function of the explanatory variables: $\pi_i=G(x_i\beta)$. Using this estimation approach in the present analysis, the log-likelihood of observation i is specified as $l_i(\beta) = y_i \log[G(x_i\beta)] + (1-y_i)\log[1-G(x_i\beta)]$ for some known function $G(.)$ satisfying $0 < G(z) < 1$ for all $z \in \Re$. The logistic function $G(.)$ is one of the most commonly used transform (Greene, 2003), devising the logit model adopted in the present analysis. Finally, because the conditional expectation function is nonlinear, the parameter value β_k does not directly measure the effect of a change in explanatory variable x_k on the mean of the dependent variable. In the present application, the marginal effect of x_k on the conditional expectation function is given by $g(x\beta)\beta_k$, where $g(z) = dG(z)/dz = \exp(z)/(1+\exp(z))^2$.

Along with the average sample values ($\overline{X}$) for the variables considered in the conditional statistical analysis, Table 3 provides maximum likelihood estimates of the marginal effects of each explanatory variable on the probability of compliance with requirements §1 - §4. The descriptive statistic shows that about 59% of the HCFs have a staff member designated for the management of the waste generated within the facility. However, only about 19% report conducting internal waste audits regularly. In addition, it is found that just 5% of the HCFs provide regular (ie, at least once a year and lasting for more than 2 hours) E&T opportunities on waste handling issues to their staff. The

descriptive statistic also shows that waste classified as hazardous accounts on average for 69% of the total waste produced, a figure that substantially exceeds the 10%-25% predicted in the World Health Organization (WHO, 2005b) guidelines. Such high hazardous waste fractions, however, are not unheard of for the type of HCFs in this sample. For example, Da Silva et al., 2005, found hazardous waste accounting for 74.7% of the total waste produced in dental offices in the State of Rio Grande do Sul-Brazil. Concerning the included control variables, the results show no statistically significant regional impacts on the probability of compliance with each of the individual regulatory requirements. Larger HCFs (ie, those having a number of collaborators equal to or higher than the median number (4) of collaborators in the sampled facilities) are more likely to comply with requirements §2 - §4 than smaller HCFs, but no statistically significant effect is found concerning the size of the HCF on the probability of compliance with requirement §1. Likewise, medical and nursing offices do not differentiate themselves from Other types of facilities (the omitted category) in compliance behavior. However, the results show that the dental clinics in the sample are more likely to comply with each of the requirements than all the other types of the HCFs. Importantly, the results show that the fraction of hazardous HCW generated by the HCFs is a significant predictor of the probability of compliance with of the considered requirements. The sign of its effects on the probability of compliance, however, is not consistent across all of the requirements. While increases in the fraction of hazardous HCW generated lead to increases in the probability of compliance with requirements §1, §2 and §4 in the 7 to 11 percentages points' range, those same increases lead to a *decrease* in the probability of compliance with requirement §3 by about 16 percentage points. Apart from the effects found for dental clinics, this is actually the strongest factor affecting the probability of compliance with the required

periodicity between collections (§3). Together, these findings suggest that the required periodicity might be too costly and unfeasible for small waste producers generating high fractions of hazardous HCW, and a review of the legislation better tailored to the periodicity of these HCFs' hazardous waste generation is recommended.

Turning to the analysis of the effects of the policy variables, the results show that conducting internal waste audits affects positively the probability of having a waste management plan as required (§4), but has no effects on compliance with any of the remaining requirements. As expected, the nomination of an individual responsible for the management of the HCW significantly contributes to the probability of compliance with each of the requirements. The results show that, ceteris paribus, HCFs that designate a staff member to manage or coordinate waste management have on average a 27 percentage points higher probability of having a waste management plan than HCFs that do not do so. Likewise, the probability of storing waste classified as hazardous in a different place from that used to store non-hazardous waste (§2), the probability that the period between collections does not exceed 7 days (§3), and the probability of storing the waste in the appropriate colored containers are, respectively, 10, 9, and 3 percentage points higher for HCFs that designate an individual responsible for the management of the HCW than for those HCFs that do not do so.

Finally, while the provision of E&T opportunities on waste handling issues to staff members does not affect compliance with requirements §1 and §3, it is one of the strongest factors affecting compliance with requirements §2 and §4. Ceteris paribus, provision of E&T opportunities increases the probability of having a waste management plan at the facility level by 22 percentage points. Similarly, all else the same, provision of E&T opportunities increases the probability of storing waste classified as hazardous in a different place from that used to store non-hazardous waste by 26 percentage

points. This requirement has a direct impact on the environment and potential critical health risks at the HCFs. This result, therefore, adds weight to the argument (eg. Botelho, 2012) that the delivery of education and training programs at the facilities' level is an essential condition to ensure a system that protects the environment and human health.

5. Conclusion

Healthcare units generate substantial amounts of hazardous or potentially hazardous wastes as by-products of their medical services. The inappropriate management of these wastes poses significant risks to people and the environment. Within the countries of the European Union (EU), the management of HCW is strictly regulated by law. Measures pertaining to the collection, storage, treatment and disposal of hazardous waste are construed to ensure that the waste management process takes place in conditions that protect the environment and human health. Despite the growing awareness by legislators that compliance with the applicable regulations is essential to achieve the best environmental protection, little is known to date about the compliance of the increasingly large numbers of private EU outpatient healthcare facilities with these measures. Using a large survey of over 700 private outpatient healthcare facilities in the EU, this study finds that overall compliance with the law is far from ideal, and identifies important sources of variability in compliance behavior with each of the measures comprising the HCW legislation. In particular, it is found that the magnitude and statistical significance of policy variables that can be manipulated at the HCFs' level are not constant across these different measures. The same finding applies with respect to general characteristics of the HCFs under scrutiny.

Importantly, it is found that the most problematic regulatory measure is the required periodicity between collections, with more than 75% of the units failing to comply with it. This requirement, however, has a direct impact on the environment. Along with the finding that HCFs generating higher fractions of hazardous HCW are also the least likely to comply with this requirement, the reported results suggests that a review of the legislation better tailored to the periodicity of these HCFs' hazardous waste generation may be needed, but also add weight to the argument that more public investments in monitoring healthcare facilities' compliance with the law in EU countries is warranted. In addition, the results show that the lack of education and training opportunities on HCW management issues impairs compliance with essential requirements regarding the storage of hazardous waste thereby endangering the environment and human health. Together, these findings suggest that along with the development of better bottom-up solutions to the HCW problem, more research and attention to the management practices of the growing number of private healthcare providers in Europe is needed to ensure a system that is economically sustainable, and protects human health and the environment.

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Table 1 – Legal requirements

§0.	Waste must be segregated at the point of generation.
§1.	Waste must be stored at a temporary storage place in specific colored containers (black containers for Group I and II waste; white containers marked with a biohazard sign for Group III waste; red containers for Group IV waste).
§2.	Group III and Group IV waste must be stored at a different place from the waste belonging to Groups I and II.
§3.	The storage place must have a minimum storage capacity corresponding to 3 days of production, and, in case the collection period exceeds those 3 days, the storage place must be equipped with a refrigeration system. In any case, the period between collections cannot exceed 7 days.
§4.	Each healthcare facility must have a waste management plan.

Table 2 – Compliance with legal requirements

Specific Legal Requirements	Percentage of compliant facilities
§0. Segregation at the point of generation	100.00
§1. Appropriate colored containers	90.55
§2. Availability of required waste storage place	30.09
§3. Period between collections ≤ 7 days	23.08
§4. Waste management plan	34.14

Table 3 –Estimates of the marginal effects of regressors on compliance with each regulatory provision

Variable	§1	§2	§3	§4	$\overline{X}$
Education and Training	*-0.004*	*0.262*	*0.013*	*0.223*	
	(0.026)	(0.087)	(0.066)	(0.095)	0.049
	[0.886]	[0.002]	[0.841]	[0.019]	
Responsible for WM	*0.028*	*0.102*	*0.092*	*0.272*	
	(0.013)	(0.035)	(0.032)	(0.034)	0.586
	[0.035]	[0.004]	[0.004]	[0.000]	
Regular Audits	*0.005*	*0.056*	*0.007*	*0.213*	
	(0.009)	(0.046)	(0.040)	(0.051)	0.189
	[0.560]	[0.227]	[0.866]	[0.000]	
Fraction of hazardous HCW	*0.072*	*0.101*	-0.155	*0.105*	
	(0.020)	(0.046)	(0.038)	(0.048)	0.690
	[0.000]	[0.028]	[0.000]	[0.027]	
≥Median number of Workers	*0.004*	*0.138*	*0.081*	*0.166*	
	(0.007)	(0.036)	(0.032)	(0.041)	0.509
	[0.588]	[0.000]	[0.011]	[0.000]	
Type of Healthcare Facility					
Dental Clinic	*0.032*	*0.130*	*-0.179*	*0.120*	
	(0.012)	(0.038)	(0.036)	(0.041)	0.529
	[0.008]	[0.001]	[0.000]	[0.003]	
Medical Office	*0.009*	*-0.043*	*-0.059*	*-0.071*	
	(0.006)	(0.042)	(0.034)	(0.043)	0.372
	[0.146]	[0.301]	[0.080]	[0.101]	
Nursing Office	*0.016*	*-0.064*	*0.035*	*-0.013*	
	(0.009)	(0.060)	(0.060)	(0.064)	0.090
	[0.082]	[0.283]	[0.560]	[0.841]	
Region of location					
North	*0.002*	*0.004*	*0.024*	*-0.010*	
	(0.006)	(0.039)	(0.035)	(0.041)	0.317
	[0.802]	[0.913]	[0.487]	[0.813]	
Alentejo	*-0.001*	*-0.022*	*-0.067*	*0.125*	
	(0.013)	(0.069)	(0.046)	(0.078)	0.077
	[0.952]	[0.752]	[0.142]	[0.111]	
Algarve	*-0.019*	*0.113*	*0.029*	*0.103*	
	(0.024)	(0.090)	(0.072)	(0.103)	0.050
	[0.441]	[0.210]	[0.686]	[0.317]	
Log-pseudolikelihood	-134.32	-420.42	-359.72	-394.16	
χ^2 statistics with 11 df	73.25	60.94	79.19	125.17	

Note: N=741; Marginal effects are in italics; Standard errors are in parentheses; p-Values are in square brackets. Wald tests for the null hypothesis that all coefficients in each model are zero have χ^2 values implying *p*-values less than 0.001.