

Borowska Mariola, Augustynowicz Anna, Czerw Aleksandra Izabela. Factors determining the financial effectiveness of outsourcing in medical entities in Poland. *Journal of Education, Health and Sport*. 2018;8(12):546-557. eISSN 2391-8306. DOI <http://dx.doi.org/10.5281/zenodo.2525716> <http://ojs.ukw.edu.pl/index.php/johs/article/view/6407> <https://pbn.nauka.gov.pl/sedno-webapp/works/893688>

The journal has had 7 points in Ministry of Science and Higher Education parametric evaluation. Part B item 1223 (26/01/2017).
1223 Journal of Education, Health and Sport eISSN 2391-8306 7

© The Authors 2018;


This article is published with open access at Licensee Open Journal Systems of Kazimierz Wielki University in Bydgoszcz, Poland


Open Access. This article is distributed under the terms of the Creative Commons Attribution Noncommercial License which permits any noncommercial use, distribution, and reproduction in any medium, provided the original author (s) and source are credited. This is an open access article licensed under the terms of the Creative Commons Attribution Non commercial license Share alike. (<http://creativecommons.org/licenses/by-nc-sa/4.0/>) which permits unrestricted, non commercial use, distribution and reproduction in any medium, provided the work is properly cited.


The authors declare that there is no conflict of interests regarding the publication of this paper.

Received: 20.11.2018. Revised: 20.12.2018. Accepted: 24.12.2018.

Factors determining the financial effectiveness of outsourcing in medical entities in Poland

Name Mariola Borowska 
Affiliation Medical University of Warsaw, Department of Health Economics and Medical Law
Country Poland
Bio Statement —

Name Anna Augustynowicz 
Affiliation Medical University of Warsaw, Department of Health Economics and Medical Law
Country Poland
Bio Statement —

Name Aleksandra Izabela Czerw 
Affiliation Medical University of Warsaw, Department of Health Economics and Medical Law
Country Poland
Bio Statement —

Principal contact for editorial correspondence.

Abstract The aim of the paper was to analyze the financial efficiency of outsourcing in connection with basic and auxiliary activity of medical entities in Poland. Research material consisted of 755 questionnaires filled in by the representatives of medical entities. Five of them were completed only partially, and thus they were not qualified for analysis, which means that complete analysis was performed in 750 medical entities, selected at random from the Register of Health Care Providers. The analysis of medical entities was performed in connection with outsourcing activities. The following auxiliary services were examined: cleaning, laundry, catering, property security and waste disposal, together with the services connected with basic activity, such as: medical staff, medical imaging, laboratory diagnostics. Each area was analyzed in connection with the reason for transferring a given activity to an external company, benefits and disadvantages obtained in connection with separating the service from the entity's structure as well as the method for monitoring the external company. Economies that medical entities gained compared to the costs of the same function before its separation were analyzed, together with the fact whether employees of the entity were given the job in the medical entity after its restructuring or not. All of the above mentioned areas were analyzed with relation to entity type, following the division into public and non-public entities.

Key words: outsourcing, health care, financial efficiency of outsourcing, medical entities

INTRODUCTION

Healthcare entities are subject to restructuring processes. Outsourcing constitutes one of the elements of this restructuration. It consists in separating some functions from the organizational structure of a healthcare entity and transferring their performance to an external contractor [1]. The most frequent reason for outsourcing and at the same time the

result achieved in short term, is the reduction of costs. Other effects include simplifying the organizational structure of a healthcare entity, improving the quality of services provided as well as the access to latest technologies and expertise. Long-term effects of outsourcing are: the increase in economic and financial efficiency, development of key areas of the entity's activity as well as its improved image [2].

The literature includes extensive presentation of experiences relating to the application of outsourcing method in healthcare in subsequent countries [2], [3], [4], [5], [6], [7]. Among the leaders of outsourcing in healthcare there are the United States and Canada, while the Netherlands lead in Europe. The outsourcing of medical imaging and IT services are the most expanded in the United States [8]. In Canada, recommended services are mainly cleaning and mass catering . In the literature one can find an interesting example of the outsourcing of medical imaging by a hospital in Pennsylvania [9]. It is based on the cooperation with service providers located in India. The hospital sends images to radiologists who prepare scan interpretation and impression. In this way, costs connected with maintaining radiologists' offices and with their remuneration are reduced and doctors employed by the hospital save their time and may concentrate on their patients. IT services outsourcing may constitute an example here, used by the hospital in California, which have implemented it in order to supervise prescriptions for narcotic medicines, constituting one of the most frequent causes of death in the United States. The IT system, introduced in the 1960s in the hospital in California, enabled the registration of all medicines prescribed by doctors. Thanks to this, errors connected with the prescribed medicines were reduced by ca. 20%. In the Netherlands, the model of a comprehensive, fully computerized system for supplying medical centers with different products have been developed, starting from beverages up to medical materials [10].

Polish literature describes the examples of outsourcing used in single medical entities. However, the results of scientific research presenting the number of entities relying on outsourcing, most frequently applied outsourcing type or its financial efficiency are absent. Financial efficiency is of particular importance in connection with the argument raised in literature that outsourcing constitutes the tool aimed at rationalizing the costs of functioning of medical entities [11].

OBJECTIVE

The aim of the paper was to analyze the financial efficiency of outsourcing in connection with basic and auxiliary activity of medical entities in Poland.

MATERIAL AND METHODS

Research material consisted of 755 questionnaires filled in by the representatives of medical entities. Five of them were completed only partially, and thus they were not qualified for analysis, which means that complete analysis was performed in 750 medical entities, selected at random from the Register of Health Care Providers.

The analysis of medical entities was performed in connection with outsourcing activities. The following auxiliary services were examined: cleaning, laundry, catering, property security and waste disposal, together with the services connected with basic activity, such as: medical staff, medical imaging, laboratory diagnostics. Each area was analyzed in connection with the reason for transferring a given activity to an external company, benefits

and disadvantages obtained in connection with separating the service from the entity's structure as well as the method for monitoring the external company. Economies that medical entities gained compared to the costs of the same function before its separation were analyzed, together with the fact whether employees of the entity were given the job in the medical entity after its restructuring or not. All of the abovementioned areas were analyzed with relation to entity type, following the division into public and non-public entities.

The study included the measurement of financial efficiency of the outsourcing of both auxiliary services as well as basic activity.

Responses provided by medical entities were analyzed with the use of statistical tests, among others Friedman test and Wilcoxon test. 95% confidence intervals were prepared, based on bimodal distribution, which were used for comparing different values in the tables and between them.

RESULTS

The study concerned 750 medical entities, including 446 public entities (59.5%) and 296 non-public entities (39.5%). Nearly 45% of medical entities employed up to 50 staff members (value measured by the number of medical staff). In the majority of cases, medical entities constituting the subject of the study were operating in villages and small towns with maximum 20 thousand inhabitants.

Table 1. Distribution of frequency for auxiliary services transferred for outsourcing.

Auxiliary services	n	%	95% CI
cleaning	373	49,7	46,2÷53,3
laundry services	427	56,9	51,6÷62,3
catering	303	40,4	33,3÷47,5
property security	490	65,3	56,7÷74,0
waste disposal	660	88,0	80,9÷95,1

n – number of entities; % - sample percentage; 95% *CI* – 95% confidence interval specified for the percentage value

Table 1 presents the distribution of frequency for auxiliary services provided by external companies in the analyzed medical entities. For each of the obtained values, 95% confidence interval was specified, based on bimodal distribution. Relying on the services of an external company for waste disposal was declared by nearly 90% of respondents. About 40% of medical entities claimed to outsource catering services.

The most frequent reason for which medical entities would choose outsourcing services consisted in high costs of employing their own staff. Waste disposal constitutes an exception here – in the majority of cases, own staff were never employed. Too high costs of employing own staff were the most frequently quoted in relation to waste disposal services and property security. The necessity of money saving was most frequently mentioned in connection with cleaning services and property security, and the least frequently for waste disposal. Outsourcing was the most often motivated by the entity's financial situation. In relation to this, it was analyzed whether medical entities managed to save money. In each of

the analyzed areas of activity economies were recorded by 30% up to 45% of respondents. Average value of the saving percentage estimated by the respondents amounted to 20.11% with standard deviation of 1.58. Confidence interval, in which the estimated economies are included with 95% certainty, extends from 16.98% to 23.3%. Economies were reported more often in connection with cleaning, laundry services, property security and less frequently when it comes to catering and waste disposal. Improvement in the quality of the provided services was more frequently quoted in connection with cleaning, laundry services and property security and less frequently for catering and waste disposal. The opinion quoting no benefits at all was not common and it usually concerned waste disposal. Disadvantages of transferring auxiliary services to external companies were not frequent. Decreased level of satisfaction from the meals consumed was the most often quoted by employees and patients in the case of transferring the provision of catering services to an external company.

The situation of employees delegated outside the medical entity was also analyzed. Average number of employees employed in the area of auxiliary services before them being transferred to external companies amounted in the entities surveyed to 16.20 at standard deviation of 3.38. Confidence interval, in which the number of staff employed in the area of auxiliary services before them being transferred to external companies is included with 95% certainty, extends from 10 to 23 persons. Employment by an external company was the most frequent in property security and happened less often in connection with cleaning services and the least frequently for waste disposal. Being delegated to another structure of the medical entity would take place less often than being employed in an external company. This refers to all types of auxiliary services.

An important aspect of the outsourcing agreement consists in the method of evaluation of outsourcing partner's activities. It was analyzed whether the entities monitored the quality and method of providing auxiliary services. Most frequently monitored activity was waste disposal, while catering was the least frequently supervised. A small percentage of medical entities organize informal internal controlling. Formalized assessment basing on the specificity of a service was quoted on average by half of the respondents in each of the five areas of auxiliary activity of a medical entity, most often with relation to waste disposal.

Table 2. Satisfaction from auxiliary services provided by external companies

Auxiliary services		Satisfaction from services			
		yes	no	partially	not applicable
cleaning	<i>n</i>	325	14	40	263
	%	43,3	1,9	5,3	35,1
laundry services	<i>n</i>	335	5	73	252
	%	44,7	0,7	9,7	33,6
catering	<i>n</i>	192	8	101	327
	%	25,6	1,1	13,5	43,6
property security	<i>n</i>	454	0	22	197
	%	60,5	0	2,9	26,3
waste disposal	<i>n</i>	602	2	27	84
	%	80,3	,3	3,6	11,2

n – number of respondents; % - sample percentage

Table 2 presents satisfaction from auxiliary services provided by external companies. Basing on Friedman test it was stated that the level of satisfaction from the realized auxiliary services differed depending on the type of service, $\chi^2(4)=103.79$, $p<0.001$. Table 4 presents the results of Wilcoxon test used as paired t-test between subsequent types of auxiliary services.

Statistically significant differences were obtained for the majority of the analyzed comparisons, with the exception of the comparison between the level of satisfaction from laundry services and cleaning as well as comparing the level of satisfaction from waste disposal and property security. The highest level of satisfaction was recorded for property security and waste disposal, lower for laundry services and cleaning and the lowest for catering services.

Table 3. Frequency distribution for basic services transferred for outsourcing.

Basic services	<i>n</i>	%	95% <i>CI</i>
Medical staff	195	26,0	22,9÷29,1
Laboratory	534	71,2	68,0÷74,4
Medical imaging	478	63,7	60,3÷67,2

n – number of entities; % - sample percentage; 95% *CI* – 95% confidence interval specified for the percentage value

Table 3 presents frequency distribution for basic activity services provided by external companies in the analyzed medical entities. 95% confidence intervals were prepared for each of the obtained values, based on bimodal distribution. Using the services of an external company in the area of laboratory diagnostics was declared by nearly 72% of respondents. Medical staff was the least frequently quoted. It is connected with the fact that often the respondents treated medical staff employed basing on contracts as their own employees and not as a form of outsourcing.

The most common reason for which medical entities would decide to use outsourcing services consisted in too high costs of employing their own staff, the necessity to establish economies as well as obtaining the access to knowledge and highest quality and technology. These three arguments were more frequently quoted in connection with laboratory services and medical imaging than when it comes to medical staff.

Medical entities paid particular attention to financial issues as outsourcing determinants. In connection with the above, it was analyzed whether medical entities managed to obtain economies. Average value of economies percentage estimated by the respondents amounted to 15.56% at standard deviation of 1.14. Confidence interval, in which the estimated economies are included with 95% certainty, extends from 13.3% to 17.8%. Increase in the quality of provided services, financial economies as well as the access to knowledge and highest quality technology were more frequently quoted in connection with medical staff and laboratory services than when it comes to medical imaging. Higher level of employee and patient satisfaction was recorded more often in the context of medical imaging than in the context of medical staff and laboratory services. It was seldom (1.9% - 3.3%) stated that an entity did not have any benefits. Disadvantages of outsourcing medical staff, laboratory services or medical imaging were rarely quoted. The most frequent of them included delays in the realization of laboratory and medical imaging services.

Employment history of the staff delegated outside the medical entity was analyzed. Average number of staff employed in connection with basic services before them being transferred for performance by external companies in the analyzed entities amounted to 9.35 with standard deviation of 1.68. Confidence interval in which the number of staff employed in connection with basic services before them being transferred for performance by external companies is included with 95% certainty extended from 6 to 13 persons. Employment by an external company was more frequent in the case of medical staff and laboratory and less frequent for medical imaging. Fewer employees were delegated to another structure of a

medical entity than employed by an external company. This concerned all types of basic services.

The next analyzed aspect consisted in the method of evaluation of outsourcing activities by a medical entity.

The most frequently conducted activity was the monitoring of laboratory services (nearly 65% of responses), the least frequent one – the monitoring of medical staff (nearly 27% of responses). Two ways of monitoring the quality of basic services transferred to external companies were identified: informal internal control as well as formal assessment based on the specific character of a given service. Formal assessment based on the specific character of a given service was conducted more often in connection with laboratory services and medical imaging (over 50% of responses) than for medical staff (nearly 15%).

Table 4. Satisfaction from basic services performed by external companies

		Satisfaction from services			
		yes	no	partially	not applicable
Basic services					
Medical staff	<i>n</i>	186	2	13	433
	%	24,8	0,3	1,7	57,7
Laboratory	<i>n</i>	499	3	28	158
	%	66,5	0,4	3,7	21,1
Medical imaging	<i>n</i>	445	3	30	176
	%	59,3	0,4	4,0	23,5

n – number of respondents; % - sample percentage

Table 4 presents Satisfaction from basic services performed by external companies. Basing on Friedman test it was stated that the level of satisfaction from the realized basic services did not depend on the type of service, $\chi^2(2)=0.40$, $p>0.05$. Satisfaction from all three service types was declared in the biggest number of cases.

DISCUSSION

The study showed that medical entities most frequently employ external companies to provide waste disposal services. Waste disposal, including the disposal of medical waste, is subject to strict guidelines, complemented with the cases of special treatment of medical waste. These guidelines are specified in the Ordinance of the Minister of Health as of 5 October 2017 on detailed medical waste treatment (Journal of Laws 2017, item 1975). These provisions describe appropriate waste segregation method as well as ventilation of rooms where the waste is stored. They also specify storage deadline as well as the handling of highly infectious waste with identified or suspected content of biological pathogenic agents qualified as category A according to point 2.2.62.1.4.1 of Annex A to the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). What

is more, hygienic requirements within the procedure of waste storage (disinfection of: hands, rooms; equipment) [12] were developed and extended. It can be assumed that part of the medical entities do not possess appropriately adapted facilities, including waste incineration plants. For this reason, these are not only financial issues, but also the inability or important difficulties to comply with legal requirements which decide that the most popular form for outsourcing auxiliary services is constituted by the outsourcing of waste disposal. For many entities this represents not only a cost-effective, but also obligatory solution [14] [15].

Catering constitutes the service which is the least frequently transferred to external providers. At the same time, catering services provided by external companies receive the least favorable assessment in terms of recipients' satisfaction. Different issues occur, such as delays in the supply of meals, their inappropriate content with regard to special nutritional needs of patients determined by their health condition. This may result from the fact that medical entities establish price of the service as the factor decisive for selecting tenderer's offer. Nevertheless, price competition often leads to the situation when the company who wants to win the tender offers very low price, making it impossible to guarantee appropriate quality of meals. Probably this is the reason why medical entities decide to conduct their own catering activity. In addition, for some managers the kitchen operating within the structure of a medical entity constitutes the source of additional income. Apart from the catering for patients, prepared meals may be offered within the framework of additional activity to visitors, staff of the medical entity as well as to patients and other persons.

Laboratory diagnostics constitutes the service included within basic activity of an entity which is the most frequently provided by external companies. It is probably connected with avoiding the necessity to invest in new equipment, incur personnel costs, conduct maintenance, participate in quality inspections, risk price changes at suppliers etc [16] [17]. Another issue lies in unquestionable advantage, in particular of network laboratories, when it comes to the economies of scale, their financial and organizational potential as well as their reach. Network laboratories perform tests at a considerably lower price than independent medical entities as they are able to negotiate lower prices for obtaining medical equipment, samples, reagents etc.

A small number of medical entities conduct the monitoring of their outsourcing partner. When it comes to auxiliary services, the most frequent activities consisted in the monitoring of waste disposal, the least frequent – the monitoring of catering services. It is connected with the finding that waste disposal constitutes the service which is the most often transferred to external service providers, while catering – the least often. In the field of services forming basic activity of a medical entity, analogous situation is observed. Monitoring of laboratory services was the most frequent, while the monitoring of medical staff – the least frequent. Formal assessment based on the specific character of a given service was conducted the most frequently in connection with waste disposal. It is linked with detailed requirements that the Legislator imposes on entities in connection with the storage and disposal of waste (Ordinance of the Minister of Health as of 5 October 2017 on detailed medical waste treatment (Journal of Laws 2017, item 1975)). When it comes to other services, conducting supervision basing on the specific character of a service is connected with additional costs that medical entities want to avoid. Informal external supervision is rarely performed as it is supposed that medical entities do not include such provisions in their outsourcing agreements.

The most frequent reason for which medical entities decide to use outsourcing services are finances. In connection with the above it was analyzed whether medical entities managed to obtain economies. In each of the analyzed fields of auxiliary activity, economies were obtained by 30% to 45% of respondents. Average value of economies percentage estimated by the respondents amounted to 20.11%, while when it comes to basic activity, average value of economies percentage estimated by the respondents amounted to 15.56%. Economies were recorded more often in the case of cleaning, laundry services and property security and less often for catering and waste disposal. Antoni Jurasz University Hospital No. 1 in Bydgoszcz constitutes an example confirming positive aspects of outsourcing with reference to financial efficiency. Since 2011, the Hospital has been cooperating with an external supplier in connection with laundry services and the rental of hospital bed linen. Economies reach the level of 10% - 15%. Space obtained after the liquidation of the laundry was adapted to serve other purposes. Funds obtained from selling hospital bed linen were invested in modern treatment techniques. Employees of the separated organizational unit were transferred to other organizational units or employed by an external company [1].

Depending on the type of separated functions, outsourcing at the Teaching Hospital in Szczecin (SPSK 2) was divided into two categories: the outsourcing of auxiliary functions and the outsourcing of basic functions. The scope of separation was complete (e.g. security and waste disposal services) or partial (e.g. cleaning services). Durability (strategic or tactical outsourcing) of the separation of medical waste disposal services constitutes an element of strategic outsourcing, as potential decision to build a new incineration plant would be permanent and important for the hospital's strategy. Having compared the costs of constructing a new incineration plant with the costs of employing an external company, the decision was made to outsource waste disposal services. The costs incurred by SPSK 2 for the disposal of 1 kg of medical waste in their own incineration facility reached in 2005 PLN 1.59, while in 2006 the waste was treated by the external company for PLN 2.53 per 1 kg. The comparison of abovementioned sums does not fully characterize Hospital's situation in view of the necessity to discontinue the exploitation of the incineration plant. If the hospital had not decided to outsource this type of service, it would have been connected with the necessity to purchase new incineration plant compliant with all technical requirements. The cost of construction of an incineration plant was estimated by another hospital in Szczecin for the amount of ca. PLN 4 million. This amount, divided into 15 years of depreciation, including service costs amounting to 5% of project value per year, at the annual quantity of medical waste amounting to 117.223 Mg, results in the estimated annual cost of treating 1 kg of waste of ca. PLN 3.98. This amount should also in addition include annual energy consumption cost (ca. PLN 50 thousand) and bank loan costs (ca. PLN 200 thousand per year), which would result in the cost of disposal of 1 kg of medical waste of ca. PLN 7, i.e. nearly three times more than the cost of employing an external service provider [13].

CONCLUSIONS

1. Within the scope of their auxiliary activity, medical entities most frequently outsource waste disposal services, which is connected not only with financial efficiency, but also with strict legislative requirements.
2. Within the scope of their basic activity, medical entities most frequently outsource laboratory diagnostics, which is most probably connected with financial efficiency and eliminating the necessity to invest in specialist equipment.

3. Outsourcing makes it possible to reduce the costs generated by subsequent auxiliary services in a medical entity as well as by basic activity services. Average value of a percent of economies is higher when it comes to the services within the scope of auxiliary activity than for the services of basic activity of a medical entity and oscillates around 18%.

REFERENCES

1. Marcinkowska E., Outsourcing w zarządzaniu szpitalem publicznym, Oficyna a Wolters Kluwer business, Warszawa 2010, s. 60-68.
2. H. Lewandowska, Outsourcing. Model zarządzania w podmiotach sektora ochrony zdrowia, Wydawnictwo Difin, Warszawa 2010, s. 200-219.
3. Wholey, D. R., Padman, R., Hamer, R., & Schwartz, S. (2001). Determinants of information technology outsourcing among health maintenance organizations. *Health Care Management Science*, 4(3), 229–239.
4. Roberts, V.(2001).Managing strategic outsourcing in the healthcare industry. *Journal of Healthcare Management*, 46(4), 239–249.
5. Manuela S. Macinati ;Outsourcing in the Italian National Health Service: findings from a national survey, *The International Journal of Health Planning and Management*, Volume 23, Issue 1, pages 21–36, January/March 2008.
6. Health Outsourcing/Backsourcing - Case studies in the Australian and Italian health sector, Suzanne Younga & Manuela S. Macinatib, *Public Management Review*, Volume 14, Issue 6, 2012.
7. Socrates J. Moschuris, Michael N. Kondylis, (2006) "Outsourcing in public hospitals: a Greek perspective", *Journal of Health Organization and Management*, Vol. 20 Iss: 1, pp.4 – 14
8. Daniel P. Lorencea, Amanda Spinkb, Healthcare information systems outsourcing, *International Journal of Information Management*, Volume 24, Issue 2, April 2004, Pages 131–145.
9. Willcocks, L., Lacity, M., & Fitzgerald, G. Information technology outsourcing in Europe and the USA: Assessment issues. *International Journal of Information Management*, 1995; 15(5): 333–351.
10. <http://www.rynekzdrowia.pl/Konferencje/Outsourcing-uslug-w-ochronie-zdrowia-doswiadczenia-i-perspektywy-rozwoju,131743.html>
11. Nowoczesne zarządzanie w opiece zdrowotnej. Instrumenty zarządzania zakładami opieki zdrowotnej, praca zbiorowa pod red. Michała Trockiego, IPIS, Warszawa 2002
12. Rozporządzenie Ministra Zdrowia z dnia 5 października 2017 r. w sprawie szczegółowego sposobu postępowania z odpadami medycznymi.
13. Kotłęga D., Nowacki P., Lewiński D., Outsourcing - teoria i zastosowanie w Szpitalu Klinicznym w Szczecinie na przykładzie usług transportu i utylizacji odpadów medycznych, Katedra i Klinika Neurologii Pomorskiego Uniwersytetu Medycznego w Szczecinie, 2014.
14. Czerw A., Religioni U., Outsourcing jako narzędzie poprawy efektywności podmiotów leczniczych, *Studia i materiały Polskiego Stowarzyszenia zarządzania wiedzą* nr 54, ISSN 1732-324X, Bydgoszcz 2011.
15. Gay Ch., Essinger J., Outsourcing strategiczny, Oficyna Ekonomiczna, Kraków 2002.

16. Kautsch M., Zarządzanie w opiece zdrowotnej – nowe wyzwania ,Oficyna Wolters Kluwer business, Warszawa 2010.
17. Lei D., Hitt M., Strategic and Restructuring and Outsourcing: The Effects of Mergers and Acquisitions and LBOs on Building Firm Skills and Capabilities, Journal of Management, Fall 1995.

SUPPLEMENTARY REFERENCES

1. Ustawa z 1987 roku O środkach farmaceutycznych, artykułach sanitarnych i aptekach.
2. Ustawa z dnia 6 września 2001 Prawo farmaceutyczne.
3. Ustawa z dnia 27 lipca 2001 roku O wyrobach medycznych.
4. Ustawa z dnia 20 maja 2010 roku O wyrobach medycznych.