

# BUSINESS CLINICS QUALIFIED FOR THE IN VITRO GOVERNMENTAL PROGRAMME WITH THE LEGAL STATUS UP TO THE END OF 2016

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## ABSTRACT

The article presents the issue of state participation in the financing of couples' infertility treatment with in vitro fertilization. The author emphasizes that highly interesting topic of clinics recommended for infertility treatment has not been sufficiently developed. This subject is systematically developed in the public discourse, but the society, still remains divided in the matter of state and municipal government participation in the funding of couples' infertility treatment with in vitro. The author presents the evolution of *Ministry's of Health In Vitro Fertilisation Programmes* which came under the governance of the *Law and Justice* party (PiS) in 2016.

**Key words:** in vitro, in vitro fertilization, in vitro governmental programme, in vitro clinics.

## INTRODUCTION

The issue of state participation in the financing of couples' infertility treatment with in vitro fertilisation is systematically developed in the public discourse, which can be exemplified by another authorial article on this subject. Heretofore, a highly interesting topic of clinics recommended for infertility treatment has not been sufficiently developed. This subject was located at the edge of moral, ethical and even legal discussions that dominated the public debate. What is more, the social consciousness in this field is certainly not high enough to write about a good knowledge of the problem in society. This justifies the need for a more thorough introduction to this topic.

At the end of 2015, the health minister signed a new edition of the state Infertility Treatment with *In Vitro Fertilisation Programme for 2016-2019*, thereby continuing the solutions of the corresponding programme for 2013-2016. After the parliamentary elections in 2015, a heated discussion broke out on this topic among politicians of the new ruling party. The discussion has also been transferred to the level of society, which still remains divided in the matter of state

and municipal government participation in the funding of couples' infertility treatment with in vitro. The implementation of the programme in 2013-2016 relates to another interesting aspect, namely the disclosure of a need to develop economic practice in terms of medically assisted procreation services. It is, therefore, worth presenting the most significant statistics, information and conclusions in this field.

On the other hand, we shall remember that the new health minister, Konstanty Radziwiłł, announced launching another alternative solution in form of so-called *Comprehensive Procreative Health Protection Programme (Ministry of Health, 2016a)* in February 2017, instead of the previous infertility treatment programme for 2016-2019. Nonetheless, it is still worth studying the practice developed under the state infertility treatment programme for 2013-2016 and propounded for 2016-2019. Due to these solutions, the principles of state participation in the financing of in vitro infertility treatment were successfully adopted for the first time in Poland.

An additional justification of necessity for the present analysis appears to be the fact that plenty of clinics, qualified for the programme for 2013-2016 and subsequently for the next period, have not finished the treatments at the moment of announcing cancellation of the programme and replacing it with a new solution prepared under the governance of the *Law and Justice* party (PiS). The legal situation formed by the end of 2016 was of a transitional character, yet, with no doubt, it was extremely important for people already undertaking treatment of medically assisted reproduction according to programmes executed by the previous government of the *Civic Platform* (PO) in collaboration with the *Polish People's Party* (PSL).

#### ACTIVITY OF INFERTILITY TREATMENT CLINICS AS A SPECIFIC INDICATION OF ECONOMIC ACTIVITY

The activity of infertility treatment clinics can be considered as an indication of economic activity. The clinics function as entities fulfilling a specific mission not only economic but also socially. What makes the activity of the above-mentioned entities specific is the fact that qualification for the implementation of the programme requires a prior guarantee of the economic activity, including a willingness to be submitted to control measures in accordance to the Act on health care services financed by public funds of 27 August 2004 (*Journal of Laws, 2016, item 1793 as amended*). Moreover, if one interprets the medical law with its reference to the economic law, it appears that clinics, performing their activities, function as so-called health care entities for which the legislator provided a special status. At this point, we should mention a so-called regulated economic activity, i.e. an activity whose pursuit requires fulfilling additional legal requirements and obligations (Brzozowska-Kruczek, 2013, p. 63). Then again, such requirements and obligations do not have to be fulfilled by other entrepreneurs performing an economic activity, which are not subjected to any

additional regulation except the Act on freedom of economic activity of 2 July 2004 (*Journal of Laws*, 2015, item 584) and accompanying provisions.

For the state programme for 2016-2019 only those clinics that met five particular requirements<sup>1</sup> have been qualified. The first group presents formal requirements, according to which a health care entity providing services of medically assisted procreation must be a health care entity of a stationary sort, providing 24-hour health care or outpatient services and be available seven days a week. A clinic must also meet formal requirements of the Act on the infertility treatment of 25 June 2015 (*Journal of Laws*, 2015, item 1087). The requirements relate to preparedness for the provision of medically assisted procreation services as well as egg, semen and embryo banks and possession of a service permit, according to the article 48 paragraph 1 of the above-named act (*Ministry of Health*, 2016b, p. 19).

The second type of requirements for running the clinic qualified for the state programme in question relates to personnel. The staff of such health care entity must consist of obstetrics and gynecology specialists or gynecological endocrinology and reproduction specialists, including at least two doctors, who perform their job in a working time equal to two full-time employments. It is essential that the employees have theoretical knowledge and a minimum three years of documented professional experience in the same field of advanced infertility treatment methods. Also, a clinic must employ a physician, biotechnologist or biologist, or a laboratory diagnostician – at least two people performing a job with a working time equal to two full-time employments. In a case of performing treatments in the clinic, the presence of an anaesthetic and intensive care specialist is required (*Ministry of Health*, 2016b, p. 19).

The third group of requirements consists of organisational directives for medically assisted procreation procedures, and the fourth of related apparatus and equipment requirements. Clinics must have a diagnostic and treatment room as well as an embryo and cryogenic laboratory together with a bank of embryos and gametes; they must also provide a participation of an anaesthetics and intensive care specialist at every treatment. Furthermore, the health care entities are obliged to provide comprehensive activities related to the usage of medically assisted reproductive procedures based on regulations of the Act on the infertility treatment. Besides that, in case of apparatus and equipment requirements the above-mentioned economic entities are obliged to have a medical ultrasound, extensively specified in the content of the state programme, at least two CO<sub>2</sub> incubators, a laminar flow cabinet with a minimum worktop temperature of 37 Celsius degrees, and a stereo microscope with a plate of identical temperature. Other required equipment and apparatus are an inverted microscope, extensively specified in the content of state programme, and a device for safe and efficient storage of embryos. Containers for a long-term storage of biological materials in liquid nitrogen, computerised data

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1 Analogous requirements were basically formed in the programme for 2013-2016. Yet, because of the more up-to-date character of the programme for 2016-2019, the author has decided to analyse the requirements from the newer programme.

archiving tools for treatment and backup power supply for cryogenic equipment and incubators are also required (*Ministry of Health, 2016b, p. 19-20*).

The last group of requirements that clinics qualified for the infertility treatment programme for 2016-2019 must meet is so-called other requirements. They relate to the documentation of the applied procedures, standards assigned by the *Polish Gynecology Society* or the guarantee of the evaluation of hormone levels used to stimulate the ovaries. What is more, the requirements include the obligation to store and document stored egg, semen and embryos, which eventually have not been used for the medically assisted procreation or the requirement of reporting infertility treatment results achieved by the clinic (*Ministry of Health, 2016a, p. 20*). All above-mentioned requirements allowed the government to have a better control over the activity of health care entities qualified for the state infertility treatment programme at the described period. In the literature, the programme is being called a therapeutic programme and the requirements prepared for the clinics allowed to execute its general legal postulates. Among the postulates, we may name such as a plan, purpose, effectiveness, safety and timeliness of health care - provided in this case to people suffering from infertility (Grabowska, Urbaniak, 2014, p. 104).

For the realisation of the above-described state programme 29 health care entities were chosen. The activity financed by the state budget was planned for the period from 1 July 2014 to 30 June 2016. Total financial assistance amounted to PLN 154 348 318.00 (Latoszek, 2014). More information is provided in the Table 1.

**Table 1.**

*The entities qualified for the programme and the subsidies received*

<b>Entity name</b>	<b>Amount (PLN)</b>
1. Private Health Care Institution Medical Center in Bydgoszcz [NZOZ Centrum Medyczne w Bydgoszczy]	2 230 470.00
2. Obstetrics and Gynaecology Center BOCIAN in Białystok [Centrum Położniczo-Ginekologiczne „Bocian” w Białymstoku]	10 241 600.00
3. INVICTA LLC in Gdańsk [INVICTA Sp. z o.o. w Gdańsku]	9 064 570.00
4. OVUM Reproductive Medicine and Andrology LLC in Lublin [OVUM Rozrodczość i Andrologia Sp. z o.o. z w Lublinie]	2 458 610.00
5. Center for Marital Infertility Treatment in Białystok [Centrum Leczenia Niepłodności Matżeńskiej w Białymstoku]	3 750 000.00
6. Health Care Center Kielce LLC [Centrum Zdrowia Kielce Sp. z o.o.]	3 206 770.00
7. Gamete – Hospital LLC and General Partners Limited Partnership in Rzgów [Gameta Szpital Sp. z o.o. i Wspólnicy Sp. k. w Rzgowie]	18 106 610.00

Entity name	Amount (PLN)
8. Provita LLC in Katowice [ <i>Provita Sp. z o.o. w Katowicach</i> ]	11 340 000.00
9. Private Health Care Institution SALVE MEDICA Sławomir Sobkiewicz in Brzeziny [ <i>NZOZ SALVE MEDICA Sławomir Sobkiewicz w Brzezinach</i> ]	2 696 090.00
10. Medical Center MATERNITY in Cracow [ <i>Centrum Medyczne Macierzyństwo w Krakowie</i> ]	7 936 280.00
11. University Clinical Hospital in Białystok [ <i>Uniwersytecki Szpital Kliniczny w Białymstoku</i> ]	6 991 810.00
12. GynCentrum Clinic LLC in Katowice [ <i>GynCentrum Clinic Sp. z o.o. w Katowicach</i> ]	6 734 968.00
13. VITROLIVE LLC in Szczecin [ <i>VITROLIVE Sp. z o.o. w Szczecinie</i> ]	4 909 550.00
14. AB OVO LLC in Lublin [ <i>AB OVO Sp. z o.o. w Lublinie</i> ]	1 494 490.00
15. INVICTA LLC in Gdańsk – a subsidiary in Warsaw [ <i>INVICTA Sp. z o.o. w Gdańsku – filia w Warszawie</i> ]	5 677 560.00
16. Health Center GAMETA GDYNIA LLC in Gdynia [ <i>Gameta Gdynia Centrum Zdrowia Sp. z o.o. w Gdyni</i> ]	5 317 080.00
17. Medical Clinic NOVUM in Warsaw [ <i>Przychodnia Lekarska NOVUM w Warszawie</i> ]	9 973 280.00
18. University Women and Infant Health Center of the Medical Warsaw University [ <i>Uniwersyteckie Centrum Zdrowia Kobiety i Noworodka Warszawskiego Uniwersytetu Medycznego</i> ]	3 830 400.00
19. Clinic ZDRÓWKO Civil Company in Niemcz [ <i>Klinika Zdrówko S.C. w Niemczu</i> ]	1 382 400.00
20. NOVOMEDICA LLC in Mysłowice [ <i>NOVOMEDICA Sp. z o.o. w Mysłowicach</i> ]	2 771 190.00
21. GMW Embrio LLC in Opolu [ <i>GMW Embrio Sp. z o.o. w Opolu</i> ]	1 760 800.00
22. ARTVIMED-Chrobry LLC in Cracow [ <i>ARTVIMED-Chrobry Sp. z o.o. w Krakowie</i> ]	7 090 700.00
23. POLAK Civil Company in Wrocław [ <i>Polak S.C. we Wrocławiu</i> ]	1 680 000.00
24. Independent Public Clinical Hospital No. 1 of the Pomeranian Medical University in Szczecin [ <i>Samodzielny Publiczny Szpital Kliniczny nr 1 Pomorskiego Uniwersytetu Medycznego w Szczecinie</i> ]	1 986 430.00

Entity name	Amount (PLN)
25. Invimed – T LLC in Warsaw [ <i>Invimed – T Sp. z o.o. w Warszawie</i> ]	10 514 000.00
26. Gyneacology and Obstetrics Hospital of the Medical University in Poznań [ <i>Ginekologiczno-Położniczy Szpital Kliniczny Uniwersytetu Medycznego w Poznaniu</i> ]	4 626 160.00
27. Infertility Treatment Center PARENS in Cracow [ <i>PARENS Centrum Leczenia Niepłodności w Krakowie</i> ]	3 510 000.00
28. PARENS LLC in Rzeszów [ <i>PARENS Sp. z o.o. w Rzeszowie</i> ]	1 597 500.00
29. Invimed – T LLC – subsidiary in Katowice [ <i>Invimed – T Sp. z o.o. – filia w Katowicach</i> ]	1 469 000.00

Source: Latoszek, 2014.

As we may notice on the basis of the information presented in the Table 1, among the clinics qualified for the state programme in question, a majority of them is placed in voivodeship cities. Three medical entities qualified for the program were stationed in: Warsaw, Cracow, Katowice and Białystok, two in each Lublin and Szczecin. One clinic represented each voivodeship of the cities such as Rzeszów, Gdańsk, Kielce, Bydgoszcz, Opole and Wrocław.

As for the subsidies granted from the state budget, we may observe a large disparity between particular health care entities. Four out of all qualified health care entities received financial assistance exceeding PLN 10 million, namely: *Obstetrics and Gynaecology Center BOCIAN in Białystok* (PLN 10 241 600.00 mln), *Invimed – T LLC in Warsaw* (PLN 10 514 000.00), *Provita LLC in Katowice* (PLN 11 340 000.00) and *Gamete – Hospital LLC and General Partners Limited Partnership in Rzgów* (PLN 18 106 610.00).

The activity of the described health care entities appears to be specific because it involves the need for meeting certain quality standards in the medical industry. Quality management is a typical development direction of contemporary enterprises in many sectors. Health care entities have also been put under pressure to continually improve management by meeting quality requirements. In 2014, all the clinics qualified for the state programme, except the clinic *AB OVO LLC in Lublin*, have dedicated certificates for the medical industry certificates ISO (*International Organisation for Standardisation*) and/or certificates CMJ (*Health Care Quality Monitoring Centre*)<sup>2</sup>.

Additionally, in a majority of the qualified clinics, a part of personnel had an ESHRE certificate to their credit. The certificate is granted to embryologists with at least ten years of work experience as well as with extensive theoretical

2 The most popular quality standards introduced in the clinics related to the realisation of medically assisted procreation were: ISO 9001 – Quality management system, ISO 15189 – System for Quality and Competence in Medical Laboratories and ISO 27001 – Information Security Management System. Compare with: A. Fedorowicz (2015).

and practical knowledge in their field. In 2014 the highest number of people holding such certificates was employed in the *Obstetrics and Gynaecology Center BOCIAN in Białystok* (5 people), *VITROLIVE LLC in Szczecin* (4 people) as well as in the *Center for Marital Infertility Treatment in Białystok* (3 persons) (Fedorowicz, 2015).

The activity of clinics qualified for the state infertility treatment with IVF programme can be analysed in terms of results of their work, that is the number of clinical pregnancies and their ratio to the total number of cell transfers. The data is summarised in Table 2.

**Table 2.**

*Efficacy of the activity of chosen\* clinics participating in the state in vitro programme (2014)*

Entity name	Number of clinical pregnancies	Percentage ratio of pregnancies number to transfers number (%)
1. INVICTA LLC in Gdańsk [ <i>INVICTA Sp. z o.o. w Gdańsku</i> ]	404	49.1
2. Center for Marital Infertility Treatment in Białystok [ <i>Centrum Leczenia Niepłodności Matżeńskiej w Białymstoku</i> ]	182	45-48
3. Gamete – Hospital LLC and General Partners Limited Partnership in Rzgów [ <i>Gameta Szpital Sp. z o.o. i Wspólnicy Sp. k. w Rzgowie</i> ]	634	No data
4. Medical Center MATERNITY in Cracow [ <i>Centrum Medyczne Macierzyństwo w Krakowie</i> ]	327	38
5. University Clinical Hospital in Białystok [ <i>Uniwersytecki Szpital Kliniczny w Białymstoku</i> ]	412	40
6. VITROLIVE LLC in Szczecin [ <i>VITROLIVE Sp. z o.o. w Szczecinie</i> ]	252	31.9
7. INVICTA LLC in Gdańsk – a subsidiary in Warsaw [ <i>INVICTA Sp. z o.o. w Gdańsku – filia w Warszawie</i> ]	167	49.1
8. Health Center GAMETA GDYNIA LLC in Gdynia [ <i>Gameta Gdynia Centrum Zdrowia Sp. z o.o. w Gdyni</i> ]	177	37

9. Medical Clinic NOVUM in Warsaw [Przychodnia Lekarska NOVUM w Warszawie]	973	43
10. NOVOMEDICA LLC in Mysłówice [NOVOMEDICA Sp. z o.o. w Mysłowicach]	64	31.4
11. GMW Embrio LLC in Opole [GMW Embrio Sp. z o.o. w Opolu]	73	44.7
12. ARTVIMED-Chrobry LLC in Cracow [ARTVIMED-Chrobry Sp. z o.o. w Krakowie]	113	39.4
13. Invimed - T LLC in Warsaw [Invimed - T Sp. z o.o. w Warszawie]	492	40
14. Gyneacology and Obstetrics Hospital of the Medical University in Poznań [Ginekologiczno-Położniczy Szpital Kliniczny Uniwersytetu Medycznego w Poznaniu]	207	31.25-39
15. Infertility Treatment Center PARENS in Cracow [PARENS Centrum Leczenia Niepłodności w Krakowie]	194	44.7
16. PARENS LLC in Rzeszów [PARENS Sp. z o.o. w Rzeszowie]	192	No data
17. Invimed - T LLC - subsidiary in Katowice [Invimed - T Sp. z o.o. - filia w Katowicach]	114	50

Note: \* - the selection criterion was the availability of data sent by the clinics about their activity in 2014. Not all clinics provided such data in time for the research published by the newspaper *Gazeta Wyborcza* in September 2014.

Source: Fedorowicz, 2015.

On the basis of the content presented in the Table 2, it appears that the efficacy of medically assisted reproductive procedures in Poland at this time differed significantly among particular health care entities. According to data of the *Ministry of Health* for 2013-2015, an efficacy measure of the medically assisted reproduction procedures applied by the clinics qualified for the programme, i.e. the percentage ratio of the number of pregnancies to the total number of transfers, was 32% (*Nasz Bocian* Foundation, 2016). This leads to the conclusion that the activity of a large part of the clinics presented in the Table 2 was more effective in helping patients in 2014 than in overall average for all clinics for the period 2013-2015. Among the strong leaders were INVICTA LLC with its subsidiaries in Gdańsk and in Warsaw as well as a subsidiary of *Invimed - T LLC in Katowice*. These three health care entities have achieved the efficacy of performed treatments at the level of 49-50%.

If we take into consideration other tendencies in the activities of clinics in question, we should highlight that all health care entities, except for the *Gyneacology and Obstetrics Hospital of the Medical University in Poznań*, performed pro-



cedures, which support in vitro fertilisation, named TESA procedures. They involve a sperm retrieval directly from the donor's testicles by a testicular puncture. Similarly, all of the health care entities qualified for the state programme, except for the *Gyneacology and Obstetrics Hospital of the Medical University in Poznań* and *GMW Embrio LLC in Opole*, performed PESA procedures. These are treatments corresponding to TESA treatments, except that they involve a sperm retrieval by epididymis punctures. The data provided by the qualified clinics also shows that almost all of them performed in vitro procedures with the use of so-called IMSI method, i.e. using morphologically selected male gamete. The method was not applied only in the clinics: *GMW Embrio LLC in Opole*, the *Infertility Treatment Center PARENS in Cracow* and *PARENS LLC in Rzeszów* (Fedorowicz, 2015).

From the patient's point of view particularly important are not only in vitro fertilisation treatments but also the fact whether a clinic provides a preimplantation genetic diagnosis. According to data collected in the analysis carried out by the newspaper *Gazeta Wyborcza* in 2014, such services were typical for all of the clinics qualified for the programme. Yet, it should be mentioned that a majority of clinics outsourced the services to subcontractors and did not provide so-called preimplantation genetic diagnosis PGD/PGS in their own genetic laboratories. The exception to the above-described situation appears to be three clinics, i.e. *INVICTA LLC in Gdańsk*, its subsidiary in Warsaw and *Medical Clinic NOVUM in Warsaw* (Fedorowicz, 2015). A propounded progress direction of the clinics' activities may be investing, in the near future, in the development of more technologically advanced facilities and infrastructure of the genetic laboratories to improve preimplantation genetic diagnosis services.

If the state programme in question will not be prolonged, then after 2016 the clinics must make long-term adjustments to new conditions of providing medically assisted procreation services. However, the completion of initialised in vitro fertilisation cycles does not have to mean the end of the access of entities in question to the public funds. The model of funding medically assisted procreation services is changing nationwide, which is a result in particular of a change in perception of this social problem by the new government. Nonetheless, it is still possible to continue the initiatives that have been introduced by various local governments in recent years. Notable examples appear to be actions of municipal authorities in such cities as Bydgoszcz (Adamkiewicz, 2016), Częstochowa (*Samorząd PAP*, 2012) and Łódź (Jędrzejczak, 2016). The exact presentation of local government participation in IVF financing in 2012-2016 has been already a subject of a separate article, written by the author of the present paper (*Medical assistance for procreation in Poland in perspective of authorities' activity at the level of local government [Medyczne wspomaganie prokreacji w Polsce w perspektywie aktywności władz na poziomie samorządu terytorialnego]*, unpublished). At this point, it should be further suggested that since 2017 there may be greater opportunities for development of clinics offering IVF. This may come as a result of growing popularity of the debate about the participation of local governments in an implementation of financial support for such health care entities.

## SUMMARY

The pattern of infertility treatment with IVF formed in Poland in 2013-2016, as well as in the West, was based on the participation of the state as a public organisation and the medical establishments as private entities. A systematic development of medically assisted procreation services, as well as of infertility treatment techniques and technologies, is a result of the public and private sector cooperation. However, the economic activity in the private sector is marked by the fact that the clinics treating infertility use a specific form of economic freedom. The freedom is limited in some way by a significant social interest, and in practice it comes down to the necessity of fulfilling a series of legal requirements, so that the entity can be qualified for the state Infertility Treatment with *In Vitro Fertilisation Programme for 2016-2019*, and to be able to provide medically assisted procreation services, in a broad sense.

It is difficult to disagree with Joanna Haberko, which states that only the activity of health care entities, which may be state co-financed, could be a real measure for pursuing of patient rights in order to provide them an access to infertility treatment to which they are legally entitled (Haberko, 2007, pp. 23-29). The infertility treatment clinics are distinctive economic entities, whose activity in practice from the beginning was a guarantee that patients will be able to use their right to treatment of this important social problem, as undoubtedly infertility should be seen. Yet, without this form of economic activity, the state would not be able to provide an effective protection of above-mentioned patient rights and their pursuing. Privatisation of the health sector is an appropriate direction to more comprehensive rights protection of patients struggling with infertility.

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